Docket No. S045912
Supreme Court of California

Carlin v. Superior Court

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Decided Aug 30, 1996

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Appeal from Superior Court of Sutter County, No. 1106 56800, Perry Parker, Judge.– *1105 *1106

– Judge of the Sutter Municipal Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

COUNSEL

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OPINION

MOSK, Acting C.J.

In this case we address the question whether a plaintiff alleging injury from ingesting a prescription drug can state a claim against the manufacturer for strict liability and breach of warranty for failure to warn about the known or reasonably scientifically knowable dangerous propensities of its product. We conclude that she can.

In our recent decision in *Anderson* v. *Owens-Corning Fiberglas Corp*. (1993) 53 Cal.3d 987 [281 Cal.Rptr. 528, 810 P.2d 549] (hereafter *Anderson*), we held generally that manufacturers are strictly liable for injuries caused by their failure to give warning of dangers that were known to the scientific community at the time they manufactured and distributed the product: "Whatever may be reasonable from the point of 1109 view of the *1109 manufacturer, the user of the product must be given the option either to refrain from using the product at all or to use it in such a way as to minimize the degree of danger." (*Id*. at p. 1003.) In so doing, we expressly applied to manufacturers of *all* products the same rule of strict liability for failure to warn of known or reasonably scientifically knowable risks that we previously applied specifically to manufacturers of prescription drugs. (*Id*. at p. 1000; see *Brown* v. *Superior Court* (1988) 44 Cal.3d 1049 [245 Cal.Rptr. 412, 751 P.2d 470] (hereafter *Brown*.) The Upjohn Company (hereafter Upjohn), a manufacturer of prescription drugs, urges us to

now reject the strict liability standard under *Anderson* for cases involving failure to warn of known or reasonably scientifically knowable risks from prescription drugs, and adopt a new standard of simple negligence for that industry only. We discern no sound basis for doing so. Accordingly, we affirm the judgment of the Court of Appeal.

I.

Plaintiff Wilma Peggy Carlin (hereafter Carlin) brought an action for damages against Upjohn for injuries she assertedly sustained from ingesting the drug Halcion, which was prescribed for her by a physician between 1987 and 1992. She claimed, as relevant here, that Upjohn was strictly liable for failing "properly to prepare and/or warn of the dangerous propensities of Halcion." She specifically alleged that Upjohn "knew that the drug Halcion was defective . . . [,] that those who were prescribed Halcion and took the same would experience, and did experience, severe physical, mental, and emotional damages/injuries and yet, notwithstanding this knowledge, [it] despicably, and in willful and conscious disregard of the safety of those who were prescribed Halcion and of the plaintiff herein, without giving any notice of the defect to the purchasers of Halcion, placed and persisted in placing Halcion into the stream of commerce. . . ." She also claimed that Upjohn was liable for breach of warranty. She alleged that it "expressly and impliedly warranted to the physicians and their health-care patients that Halcion was a prescription drug fit for the use for which it was intended and was of merchantable quality" despite the fact that the product "was unfit and unsafe for ingestion by health-care patients in light of its known propensity to cause serious side-effects, including, but not limited to, physical, mental and emotional injuries to persons ingesting Halcion. . . ."

Upjohn demurred, alleging, inter alia, that Carlin failed to state facts sufficient to constitute a cause of action for strict liability or for breach of warranty. It argued that, under California law, no cause of action for strict liability or breach of warranty can be stated against a prescription drug manufacturer based on failure to warn. The 1110 superior court sustained the *1110 demurrer as to those causes of action without leave to amend. Carlin petitioned for a writ of mandate. The Court of Appeal issued an alternative writ of mandate; after briefing and oral argument, it issued a peremptory writ of mandate, directing the superior court to vacate its order sustaining the demurrer to the causes of action for strict liability and breach of warranty and to enter a new order overruling the demurrer. We granted review.

II.

(1a) Upjohn contends that the Court of Appeal erred in vacating the superior court's order sustaining a demurrer on Carlin's cause of action for strict liability for failure to warn. It argues that California courts have "long refused to expand the scope of potential liability of prescription pharmaceutical manufacturers beyond traditional negligence principles." Not so. In prior cases, we have expressly and repeatedly applied a strict liability standard to manufacturers of prescription drugs for failure to warn of known or reasonably scientifically knowable risks. We merely reaffirm those precedents here.

In *Anderson,* we summarized prior case law and outlined the general principles of strict liability as they have been applied by California courts for over three decades. (*Anderson, supra,* 53 Cal.3d at pp. 994-1003.) **(2)** As we explained therein, under our doctrine of strict liability, first announced in *Greenman* v. *Yuba Power Products, Inc*. (1963) 59 Cal.2d 57 [27 Cal.Rptr. 697, 377 P.2d 897, 13 A.L.R.3d 1049], a manufacturer "`is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.' . . . `The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves.' . . . [¶]

Strict liability, however, was never intended to make the manufacturer or distributor of a product its insurer. `From its inception, . . . strict liability has never been, and is not now, *absolute* liability . . .' . . . [¶] Strict liability has been invoked for three types of defects — manufacturing defects, design defects, and `warning defects,' i.e., inadequate warnings or failures to warn." (*Anderson, supra,* 53 Cal.3d at pp. 994-995; see *Barker* v. *Lull Engineering Co*. (1978) 20 Cal.3d 413 [143 Cal.Rptr. 225, 573 P.2d 443, 96 A.L.R.3d 1].)

(3) We specifically addressed the issue "whether knowledge, actual or constructive, is a component of strict liability on the failure-to-warn theory." (*Anderson, supra,* 53 Cal.3d at p. 990.) We concluded that it is. "The California courts, either expressly or by implication, have to date required
1111 *1111 knowledge, actual or constructive, of potential risk or danger before imposing strict liability for a failure to warn." (*Id*. at p. 991.) We affirmed that "California is well settled into the majority view that . . .[¶] . . . knowledge or knowability is a component of strict liability for failure to warn." (*Id*. at p. 1000.)

(1b) Although *Anderson* involved an action against a manufacturer of asbestos, we relied extensively on cases involving a variety of products, including prescription drugs. In particular, we were guided by our prior decision in *Brown, supra,* 44 Cal.3d 1049, in which we refused to extend strict liability to the failure to warn of risks that were unknown or *unknowable* at the time of distribution. "As we stated [in *Brown*], if a manufacturer could not count on limiting its liability to risks that were known or knowable at the time of manufacture or distribution, it would be discouraged from developing new and improved products for fear that later significant advances in scientific knowledge would increase its liability. . . . [A] manufacturer is not strictly liable for injuries caused by a prescription drug so long as it was properly prepared and accompanied by warnings of its dangerous propensities that were either known or scientifically knowable at the time of distribution." (*Anderson, supra,* 53 Cal.3d at p. 999.) We concluded that the holding in *Brown* applied to all products, not only to prescription drugs: " *Brown*'s logic and common sense are not limited to drugs. In recognizing the extent to which the majority rule pervades California precedents in both drug and nondrug cases, *Brown* clearly implied that knowledge is also a component of strict liability for failure to warn in cases other than prescription drug cases." (*Id*. at p. 1000; see also *Vermeulen* v. *Superior Court* (1988) 204 Cal.App.3d 1192, 1206 [251 Cal.Rptr. 805] ["We . . . do not interpret *Brown*'s analysis of the failure to warn issue to necessarily be limited to prescription drug cases. The same rationale applies equally to other products."].)[1] **(4)** We recognized that the knowledge or knowability requirement for failure to warn infuses some negligence concepts into strict liability cases.
1112 *1112 (*Anderson, supra,* 53 Cal.3d at p. 1001.) Indeed, in the failure-to-warn context, strict liability is to some extent a hybrid of traditional strict liability and negligence doctrine. As we explained, however, "the claim that a particular component `rings of' or `sounds in' negligence has not precluded its acceptance in the context of strict liability." (*Ibid*.) Indeed, "the strict liability doctrine has incorporated some well-settled rules from the law of negligence and has survived judicial challenges asserting that such incorporation violates the fundamental principles of the doctrine." (*Id*. at p. 1002.) Thus, although *Anderson,* following *Brown,* incorporated certain negligence concepts into the standard of strict liability for failure to warn, it did not thereby adopt a simple negligence test.[2]

[1] In view of our express and extensive reliance in *Anderson* on our rationale in *Brown* — which involved only prescription drugs — Justice Baxter's suggestion that *Anderson* may not properly be understood as "necessarily" applying to prescription drugs is unfounded. (Dis. opn. of Baxter, J., *post,* at p. 1155.) Although *Anderson*

involved a manufacturer of asbestos, its holding concerning the application of strict liability in failure-to-warn cases was, on its face, intended to apply generally to manufacturers of all products. To the extent that Justice Baxter purports to find any support in the dissenting opinion in *Anderson,* he is unpersuasive. The *Anderson* dissent expressed disagreement with the majority's conclusion that manufacturers generally should be liable only for failure to warn of known or knowable risks — as opposed to liability for failure to warn of risks *regardless* of whether they were known or knowable — and argued that such a limited form of strict liability should apply *only* to drug manufacturers. (*Anderson, supra,* 53 Cal.3d at pp. 1005-1008, conc. dis. opn. of Mosk, J.) The majority in *Anderson* rejected that approach. In so doing, they not only considered, but, in effect, adopted the public policy rationale of *Brown* with regard to *all* manufacturers.

[2] We found support for the standard we adopted in *Brown* in the Restatement Second of Torts section 402A, comment k, which appears under the topic of "Strict Liability." (Rest.2d Torts, § 402A, com. k, pp. 353-354.) We noted in *Brown* that imposing liability only if the manufacturer knew or should have known of a defect "sets forth a test which sounds in negligence." (*Brown, supra,* 44 Cal.3d at p. 1059, fn. 4.) We did not, as Upjohn erroneously contends, thereby establish that the standard for failure to warn is simple negligence. Rather, as *Anderson* explains, we merely rejected a standard of liability that, by imposing liability for *unknown and unknowable* risks, would be tantamount to "absolute liability."

"[F]ailure to warn in strict liability differs markedly from failure to warn in the negligence context. Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Thus, in strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial. [¶] Stated another way, a reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacturer's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles. In contrast, under strict liability principles the manufacturer has no such leeway; the manufacturer is liable if it failed to give warning of dangers that were known to the scientific community at the time it manufactured or distributed the product." (*Anderson, supra,* 53 Cal.3d at pp. 1002-1003, fn. omitted.) Similarly, a manufacturer could not escape liability under strict liability principles merely because its failure to warn of a known or reasonably scientifically
1113 knowable *1113 risk conformed to an industry-wide practice of failing to provide warnings that constituted the standard of reasonable care.[3] **(5)** We explained the policy behind our strict liability standard for failure to warn as follows: "`When, in a particular case, the risk qualitatively (e.g., of death or major disability) as well as quantitatively, on balance with the end sought to be achieved, is such as to call for a true choice judgment, *medical or personal,* the warning must be given. . . .' [Citation.] Thus, the fact that a manufacturer acted as a reasonably prudent manufacturer in deciding not to warn, while perhaps absolving the manufacturer of liability under the negligence

theory, will not preclude liability under strict liability principles if the trier of fact concludes that, based on the information scientifically available to the manufacturer, the manufacturer's failure to warn rendered the product unsafe to its users." (*Anderson, supra,* 53 Cal. 3d at p. 1003, italics added, quoting *Davis* v. *Wyeth Laboratories, Inc*. (9th Cir. 1968) 399 F.2d 121, 129-130 [applying strict liability to a manufacturer of prescription drugs].)

[3] In *Anderson,* we explained that our definition of constructive knowledge — i.e., what is "reasonably scientifically knowable" — is derived from the Restatement Second of Torts section 402A, comment j, page 353, which refers to knowledge obtainable "`by the application of reasonable, developed human skill and foresight.'" (*Anderson, supra,* 53 Cal.3d at p. 1002, fn. 13; see *Brown, supra,* 44 Cal.3d at p. 1069.) The actual knowledge of the individual manufacturer, even if reasonably prudent, is not the issue. We view the standard to require that the manufacturer is held to the knowledge and skill of an expert in the field; it is obliged to keep abreast of any scientific discoveries and is presumed to know the results of all such advances. We also note that both *Brown* and *Anderson* require that the knowledge element must exist at the time of distribution. As we explained in *Brown,* "a manufacturer's knowledge should be measured at the time a drug is distributed because it is at this point that the manufacturer relinquishes control of the product." (*Brown, supra,* 44 Cal.3d at p. 1060, fn. 8.) Obviously, subsequently developed scientific data would not be controlling.

(1c) Upjohn and amici curiae argue that applying *Anderson* will place manufacturers of prescription drugs in an untenable position because they must comply with regulations set by the Food and Drug Administration (hereafter FDA), which may preclude them from labeling drugs with warnings of certain side effects. They also contend that *Anderson* would result in overlabeling of pharmaceuticals. Neither claim withstands scrutiny.

We are unpersuaded by Upjohn's argument that a strict liability standard for failure to warn about known or reasonably scientifically knowable risks from prescription drugs is inconsistent with federal regulatory policy. Upjohn concedes that FDA regulations do not expressly preempt common law tort remedies for failure to warn or occupy the entire field of regulation. As numerous courts have concluded, Congress evinced no intention of preempting state tort liability for injuries from prescription drugs. (See, e.g., *Feldman* v. *Lederle Laboratories* (1991) 125 N.J. 1114 117, 147 [592 A.2d 1176, 1192] *1114 ["[W]e find nothing in the federal scheme to support the assertion that manufacturers of prescription drugs and antibiotics who literally comply with [FDA regulations] must be immune from state tort liability for injuries caused by their products."]; *Abbot by Abbot* v. *American Cyanamid Co*. (4th Cir. 1988) 844 F.2d 1108, 1112 [98 A.L.R.Fed. 107] [federal law does not preempt imposition of state common law liability for failure to warn, despite the fact that labeling, "once approved, cannot be changed without FDA approval."]; *Mazur* v. *Merck Co., Inc*. (E.D.Pa. 1990) 742 F. Supp. 239, 247 ["[M]ere compliance with an FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant. . . .[¶] . . . State tort law is intended to supplement federal regulation . . . ."]; cf. *Medtronic, Inc*. v. *Lohr* (1996) 518 U.S. ___, ___ [135 L.Ed.2d 700, 725-726, 116 S.Ct. 2240] (plur. opn. of Stevens, J.) [negligence and strict liability claims for failure to warn about risks of a medical device were not preempted by federal regulations].)

We disagree with Carlin's argument, however, that FDA regulations are essentially irrelevant in a common law action for failure to warn. We reiterate that strict liability for failure to warn *is*

not absolute liability. Under *Anderson,* drug manufacturers are not strictly liable for a risk that was not known or reasonably scientifically knowable. In this context, it is significant that the FDA *precludes* drug manufacturers from warning about every conceivable adverse reaction; they may warn only if there exists significant medical evidence of a possible health hazard. They are also specifically precluded from warning of adverse reactions when differences of opinion exist within the medical community with regard to potential adverse reactions. (See 21 C.F.R. § 201.57(d) (e) (1996) [requiring that warnings shall only be of known hazards, not theoretical hazards]; *id.,* § 1.21(c)(1) [prohibiting the inclusion of differing opinions regarding contraindications, precautions, adverse reactions, and other product hazards on drug warning labels].) At the same time, however, they are required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." (*Id.,* § 201.57(e).)

In appropriate cases, FDA action or inaction, though not dispositive, may be admissible under *Anderson* to show whether a risk was known or reasonably scientifically knowable. (Cf. *Hatfield* v. *Sandoz-Wander, Inc*. (1984) 124 Ill. App.3d 780, 787 [80 Ill.Dec. 122, 464 N.E.2d 1105, 1109] [evidence of compliance with FDA requirements is admissible as relevant evidence in a strict tort liability case on the issue whether a
1115 pharmaceutical manufacturer *1115 failed to provide adequate warnings]; *Proctor* v. *Davis* (1995) 275 Ill. App.3d 593, 604 [211 Ill.Dec. 831, 656 N.E.2d 23, 29] [accord].) Similarly, a drug manufacturer could present evidence to show that there was no "reasonably scientifically knowable risk" because, at the time of distribution, the cause of the alleged adverse effect was too speculative to have been reasonably attributable to the drug by a scientist conducting state-of-the-art research. Thus, when a plaintiff's claim is based on an allegation that a particular risk was "reasonably scientifically knowable," an inquiry may arise as to what a reasonable scientist operating in good faith should have known under the circumstances of the evidence. As we emphasized in *Anderson,* we do not altogether reject strict liability in the failure-to-warn context — for drugs or any other products — simply because some considerations of reasonableness sounding in negligence may be required. (*Anderson, supra,* 53 Cal.3d at pp. 1001-1002.)[4]

[4] We reject the suggestion of the dissenting opinion that the extensive regulation by the FDA of drug labeling should require us to create a new exception to the rule in *Anderson* unique to drug manufacturers. The fact that the pharmaceutical drug industry is highly regulated does not distinguish it from numerous other industries. Moreover, as the dissenting opinion concedes, the FDA's approval of a particular warning is not determinative of liability. Nor have our courts adopted the approach of the narrow line of cases cited by the dissenting opinion which would insulate manufacturers for failure to warn if they merely gave FDA-approved warnings. It is a very different thing, however, to hold, as we do here, that a pharmaceutical manufacturer may not be held liable for failing to give a warning it has been *expressly precluded* by the FDA from giving.

Moreover, in the case of an alleged "known" risk, if state-of-the-art scientific data concerning the alleged risk was fully disclosed to the FDA and it determined, after review, that the pharmaceutical manufacturer was *not permitted to warn* — e.g., because the data was inconclusive or the risk was too speculative to justify a warning — the manufacturer could present such evidence to show that strict liability cannot apply; the FDA's conclusion that there was, in effect, no "known

risk" is controlling. (See *Feldman* v. *Lederle Laboratories, supra,* 125 N.J. at p. 135 [592 A.2d at p. 1185] ["conflict preemption" occurs when compliance with both federal and state requirements is impossible].)

We are also unpersuaded by Upjohn's assertion that applying strict liability to claims of injury for failure to warn will inevitably result in manufacturers inundating consumers with warnings of even speculative risks from prescription drugs. In *Finn* v. *G.D. Searle Co*. (1984) 35 Cal.3d 691, 701 [200 Cal.Rptr. 870, 677 P.2d 1147], we addressed the potential problems of overlabeling: "[E]xperience suggest[s] that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice 1116 of any and every hint of danger, *1116 thereby inevitably diluting the force of any specific warning given." (See *Anderson, supra,* 53 Cal.3d at p. 1002, citing *Finn*.) The application of the failure-to-warn theory to pharmaceuticals requires determinations whether available evidence established a causal link between an alleged side effect and a prescription drug, whether any warning should have been given, and, if so, whether the warning was adequate. These are issues of fact involving, inter alia, questions concerning the state of the art, i.e., what was known or reasonably knowable by the application of scientific and medical knowledge available at the time of manufacture and distribution of the prescription drug. They also necessarily involve questions concerning whether the risk, in light of accepted scientific norms, was more than merely speculative or conjectural, or so remote and insignificant as to be negligible.[5]

[5] Justice Kennard's concurring and dissenting opinion is simply wrong in asserting that we would impose on prescription drug manufacturers a duty to warn of "every arguable risk." (Conc. and dis. opn. of Kennard, J., *post,* at p. 1131.) Justice Kennard also suggests that the costs of tort liability have been "excessive" in the case of such prescription drugs as the vaccines for swine flu, diphtheria-pertussis-tetanus, and polio. (*Id*. at p. 1127.) Perhaps so. But when a vaccine or other drug poses a severe *known risk,* albeit to a small proportion of patients, it is unclear how altering the burden of proof for failure to warn as she suggests would reduce those costs — unless the inevitable result would be to deprive an innocent injured person of any remedy.

Moreover, in the case of prescription drugs, the duty to warn runs *to the physician,* not to the patient. (See, e.g., *Brown, supra,* 44 Cal.3d at pp. 1061-1062; *Stevens* v. *Parke, Davis Co*. (1973) 9 Cal.3d 51, 65 [107 Cal.Rptr. 45, 507 P.2d 653, 94 A.L.R.3d 1059] ["In the case of medical prescriptions, `if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed."]; but see *Davis* v. *Wyeth Laboratories, Inc., supra,* 399 F.2d at p. 131 [exception where prescription drug "was not dispensed as such," but administered in mass immunization program].) Thus, a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community. (See *Plenger* v. *Alza Corp*. (1992) 11 Cal.App.4th 349, 362 [13 Cal.Rptr.2d 811] ["We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the consumer, in this case the physician."]; *Proctor* v. *Davis, supra,* 275 Ill. App.3d at pp. 605-606 [656 N.E.2d at p. 31] [pharmaceutical manufacturer need not provide warning of risks known to the medical community].)[6]

[6] Although Justice Kennard conjectures that physicians "may be overwhelmed by excessive warnings" if manufacturers must warn of known or scientifically knowable

> risks under this standard (conc. and dis. opn. of Kennard, J., *post,* at p. 1126), there is no evidence that any such problem has emerged or that patients have suffered any detriment, despite the fact that strict liability has long been the rule in California.

Nor does Upjohn offer any sound public policy rationale for departing from *Anderson* concerning
1117 the liability of manufacturers of prescription *1117 drugs for failure to warn of known or reasonably scientifically knowable risks. Thus, we are unpersuaded by the argument, purportedly derived from our reasoning in *Brown,* that manufacturers of prescription drugs should be exempt from the strict liability duty to warn because they might otherwise refrain from developing and marketing drugs, including "cutting-edge vaccines to combat human immunodeficiency virus (HIV)" and other diseases. Our rationale in *Brown,* which involved strict liability for *design defects,* is inapplicable: unlike strict liability for design defects, strict liability for failure to warn does not potentially subject drug manufacturers to liability for flaws in their products that they have not, and could not have, discovered. Drug manufacturers need only warn of risks that are *actually known or reasonably scientifically knowable*.

Upjohn offers no clear or sufficient basis for concluding that research and development will inevitably decrease as a result of imposing strict liability for failure to warn of *known or reasonably scientifically knowable* risks; indeed, requiring manufacturers to internalize the costs of failing to determine such risks may instead *increase* the level of research into safe and effective drugs. In any event, we see no reason to depart from our conclusion in *Anderson* that the manufacturer should bear the costs, in terms of
1118 preventable injury or death, of its own failure to provide adequate warnings of known or reasonably scientifically knowable risks. As we observed: "Whatever may be reasonable from the point of view of the manufacturer, the user of the product must be given the option either to refrain from using the product at all or to use it in such a way as to minimize the degree of danger." (*Anderson, supra,* 53 Cal.3d at p. 1003.) Although *Anderson* itself involved a nondrug, asbestos, our conclusion therein applies with equal force to prescription drugs.[7]

> [7] We are also unpersuaded by the suggestion of the dissenting opinion that we should create a new exception solely for drug manufacturers because some commentators have suggested in law review articles that the adequacy of warnings is a subset of the question of the acceptability of the basic design of a product. Equally unpersuasive is the dissenting opinion's suggestion that we should be guided by the fact that some of these same commentators have proposed that the Restatement Third of Torts — which has not been promulgated and, indeed, is still only at the "tentative draft" stage — should adopt a "reasonableness" standard and entirely abandon *any* standard of strict liability for failure to warn. Both arguments might conceivably support reversing *Anderson* altogether — an approach that even the dissenting opinion here rejects — but they do not support creating individual exceptions to a general rule of strict liability for failure to warn, e.g., only for drug manufacturers or only for highly regulated industries. Indeed, it would hardly serve to clarify the common law of products liability to create a patchwork of different rules for different types of manufacturers.

III.

(6) Upjohn also contends that the Court of Appeal erred in vacating the superior court's order sustaining demurrer on Carlin's cause of action for *1118 breach of warranty. It argues that *Brown* precludes any such cause of action for breach of warranty against manufacturers of prescription drugs. Not so. In *Brown,* we held only that "a manufacturer of prescription drugs is not strictly

liable for injuries caused by such a defect that is *neither known nor knowable at the time the drug is distributed*" and that, accordingly, an action for breach of warranty for such *unknown defect* does not lie against drug manufacturers. (*Brown, supra,* 44 Cal.3d at p. 1072, italics added.) That reasoning is inapplicable here. Like her claim for failure to warn, Carlin's breach of warranty claim is premised on failure to warn of a known or reasonably scientifically knowable defect.[8] **(7)** We emphasize, however, that the "consumer expectation" aspect of a breach of warranty action is subject, in the prescription drug context, to the general rule, discussed above, that warnings concerning the drug's properties are properly directed to the *physician* rather than the patient. (*Brown, supra,* 44 Cal.3d at pp. 1061-1062 ["[A] patient's expectations regarding the effects of [a prescription] drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties."].) Thus, for purposes of liability for breach of warranty, ordinarily "it is the prescribing doctor who in reality stands in the shoes of `the ordinary consumer.'" (*Carmichael* v. *Reitz* (1971) 17 Cal.App.3d 958, 989 [95 Cal.Rptr. 381].)

IV.

For these reasons, we conclude that the Court of Appeal in this case correctly applied *Anderson* and *Brown* in directing the superior court to vacate its order sustaining Upjohn's demurrer to the causes of action for strict liability and breach of warranty. Accordingly, we affirm the judgment of the Court of Appeal.

Werdegar, J., Spencer, J.,– and Vogel (C.S.), J.,† concurred.

– Presiding Justice of the Court of Appeal, Second Appellate District, Division One, assigned by the Acting Chief Justice pursuant to article VI, section 6 of the California Constitution.

† Presiding Justice of the Court of Appeal, Second Appellate District, Division Four, assigned by the Acting Chief Justice pursuant to article VI, section 6 of the California Constitution.

KENNARD, J., Concurring and Dissenting.

The manufacture of prescription drugs, a multibillion-dollar industry, has provided many of the 20th *1119 century's greatest success stories and some of its worst tragedies. Because they cure disease, alleviate pain, and prolong life, prescription drugs have been a great benefit to society. But prescription drugs sometimes cause severe complications and side effects, inflicting great anguish as well as temporary and even permanent disability on some individuals.

This court's task in the present case is to set rules defining prescription drug manufacturers' tort liability for personal injuries caused by their products' side effects. More particularly, the task is to determine under what circumstances a drug manufacturer should be held liable in tort for personal injury damages proximately caused by a failure to warn about the possibility of a particular drug complication.

The majority holds that a prescription drug manufacturer is liable in tort for all drug-related injuries about which it did not warn, provided only that the risk of injury was either actually known or in some manner scientifically ascertainable by the manufacturer when it distributed the drug. In his dissent, by contrast, Justice Baxter proposes that a prescription drug manufacturer be held liable for failure to warn of possible drug-related injuries only if the person injured by the drug succeeds in proving that the manufacturer's decision not to warn was unreasonable.

I find neither approach entirely satisfactory. Combining what I view as the best features of both, I would hold that initially, to establish a prima facie case, a person seeking damages for drug-related injures on a failure-to-warn theory

need prove only that at the time of distribution the manufacturer either knew or should have learned, through the application of commonly accepted scientific methods and reasonably available technologies, of the particular risk of harm; but I would hold also that after the party seeking recovery makes this showing, the manufacturer may defend on the basis that it acted reasonably, in light of all relevant considerations, in not warning of the particular risk.

I.

What standard of liability should govern when a consumer is injured by a properly manufactured drug, but the manufacturer has not warned of the drug's association with the type of injury suffered? That is the issue here. Because failure-to-warn liability for injuries caused by a drug is part of the larger field of products liability law, I begin with a discussion of the development and current state of that body of law.

Under the common law as it existed before the development of products liability law, an injured consumer could recover only under contractual
1120 *1120 warranty law, which limited recovery to those who "stood in privity of contract" — that is, the immediate purchasers of the defective product. (Prosser Keeton on Torts (5th ed. 1984) § 96, p. 681.) All too often, however, consumers lacked such privity because they had bought the product not from the manufacturer directly but from intermediaries such as retailers. Disclaimers of any warranty by the manufacturer erected yet another obstacle to recovery. (*Ibid*.)

The inadequacy of the protection afforded injured consumers under contract law eventually led the courts to extend the existing fault-based tort concept of negligence to the area of products liability. (*MacPherson* v. *Buick Motor Co*. (1916) 217 N.Y. 382 [111 N.E. 1050]; see generally, Prosser Keeton on Torts, *supra,* § 96, pp. 682-683; Prosser, *The Assault Upon the Citadel* (*Strict Liability to the Consumer*) (1960) 69 Yale L.J. 1099, 1100-1103.) Serious impediments to recovery continued to exist, however, even under negligence law. For instance, the injured consumer, because of lack of knowledge about the manufacturing process, was not ordinarily in a position to identify the cause of a defect or to show that the defect had resulted from a manufacturer's failure to act reasonably. (Prosser, *The Assault Upon the Citadel* (*Strict Liability to the Consumer*), *supra,* 69 Yale L.J. at p. 1116.) To ensure adequate protection to the user of a manufactured product, several legal scholars and jurists, most notably Justice Traynor of this court, adopted the view that a manufacturer should be held liable for defective product injuries regardless of its negligence. (*Escola* v. *Coca Cola Bottling Co*. (1944) 24 Cal.2d 453, 462-463, 467 [150 P.2d 436] (conc. opn. of Traynor, J.).)

This concept, referred to as products liability or strict liability in tort and extending not only to the manufacturer but to all others in the chain of distribution, ultimately became the law. (Prosser, *The Fall of the Citadel* (*Strict Liability to the Consumer*) (1966) 50 Minn. L.Rev. 791, 791-805.) California was the first to embrace this concept when, in 1963, in the landmark case of *Greenman* v. *Yuba Power Products, Inc*. (1963) 59 Cal.2d 57 [27 Cal.Rptr. 697, 377 P.2d 897, 13 A.L.R.3d 1049], this court held: "A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." (*Id*. at p. 62; see generally, Prosser, *The Fall of the Citadel* (*Strict Liability to the Consumer*), *supra,* 50 Minn. L.Rev. at pp. 803-805.)

As this court has acknowledged, "the very purpose of our pioneering efforts in this field was to relieve the plaintiff from problems of proof inherent in pursuing negligence (*Escola* v. *Coca*
1121 *Cola Bottling Co., supra,* *1121 24 Cal.2d 453, 461-462 (Traynor, J. concurring)) and warranty (*Greenman* v. *Yuba Power Products, Inc., supra,* 59 Cal.2d 57, 63) remedies, and thereby `to insure that the costs of injuries resulting from defective

products are borne by the manufacturers. . . .' (*Id.*; see *Price* v. *Shell Oil Co*. [1970] 2 Cal.3d 245, 251 [85 Cal.Rptr. 178, 466 P.2d 722].)" (*Cronin* v. *J.B.E. Olson Corp*. (1972) 8 Cal.3d 121, 133 [104 Cal.Rptr. 433, 501 P.2d 1153], ellipses in *Cronin*.)

The concept of products liability then spread nationwide. In 1965, products liability was embraced by the American Law Institute (hereafter ALI) when it adopted section 402A of the Restatement Second of Torts. That section states that a seller of a "product in a defective condition [that is] unreasonably dangerous to the user or consumer" is liable for physical harm caused by the product. (Rest.2d Torts, § 402A, pp. 347-348.) Soon most jurisdictions recognized some form of strict liability for defective products. (Prosser Keeton on Torts, *supra,* § 99, p. 694.)

Products liability is not absolute liability, however; a manufacturer is not the insurer of the product. (See, e.g., *Anderson* v. *Owens-Corning Fiberglas Corp*. (1991) 53 Cal.3d 987, 1003-1004 [281 Cal.Rptr. 528, 810 P.2d 549]; *Daly* v. *General Motors Corp*. (1978) 20 Cal.3d 725, 733 [144 Cal.Rptr. 380, 575 P.2d 1162].) A plaintiff must still prove that the product was defective.

"Strict liability has been invoked for three types of defects — manufacturing defects, design defects, and `warning defects,' i.e., inadequate warnings or failures to warn." (*Anderson* v. *Owens-Corning Fiberglas Corp., supra,* 53 Cal.3d at p. 995; see *Barker* v. *Lull Engineering Co*. (1978) 20 Cal.3d 413 [143 Cal.Rptr. 225, 573 P.2d 443, 96 A.L.R.3d 1].) A manufacturing defect occurs when a product does not conform to the manufacturer's intended design (*Brown* v. *Superior Court* (1988) 44 Cal.3d 1049, 1057 [245 Cal.Rptr. 412, 751 P.2d 470]); a design defect occurs either when the design of the product fails to meet consumer expectations as to safety or when, on balance, the risk of danger inherent in the challenged design outweighs the benefits of the design (*Soule* v. *General Motors Corp*. (1994) 8 Cal.4th 548, 566-567 [34 Cal.Rptr.2d 607, 882 P.2d 298]); a "warning defect" occurs when a manufacturer has issued no warnings or has failed to adequately warn of dangers posed by the product (see *Anderson* v. *Owens-Corning Fiberglas Corp., supra,* 53 Cal.3d at p. 995). The issue here pertains to the third of these categories — liability for a prescription drug manufacturer's failure to warn.

Courts and commentators have long noted that prescription drugs pose unique products liability issues, and that expansive liability for drug-related
1122*1122 injuries could deter manufacturers from developing and marketing medical drugs of benefit to society. During the discussion of a draft of what later became section 402A of the Restatement Second of Torts, a member of the ALI proposed that drugs be expressly exempted from section 402A because imposing products liability on drugs might stifle medical research and testing. (*Brown* v. *Superior Court, supra,* 44 Cal.3d at pp. 1057-1058, quoting 38 ALI Proc. 19, 90-98 (1961).) In response, Dean Prosser, who was the reporter for the Restatement Second of Torts, suggested that the issue be dealt with in a comment to section 402A. (44 Cal.3d at p. 1058.) This led to the drafting, and approval, of comment k. (See Comment, *Comment K Immunity to Strict Liability: Should all Prescription Drugs be Protected?* (1989) 26 Hous. L.Rev. 707, 736 ["the beneficial nature of prescription drugs provides the very reason for excepting them from standard rules of strict liability"].)

Comment k to section 402A of the Restatement Second of Torts recognizes the significant risk to the public interest presented by imposing excessive liability on the manufacturer of prescription drugs. Under the heading "Unavoidably unsafe products," comment k observes that commonly used drugs, while highly beneficial, are often incapable of being made entirely safe. It then notes: "It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no

assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk." (Rest.2d Torts, § 402A, com. k, p. 354.) It concludes that a manufacturer of drugs that are sold with a proper warning "where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." (*Ibid*.)

Courts and commentators have debated the exact scope and meaning of comment k to section 402A of the Restatement Second of Torts. (See, e.g., Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K* (1985) 42 Wn. Lee L.Rev. 1139 [discussing various possible interpretations of comment k]; Henderson Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts* (1992) 77 Cornell L.Rev. 1512, 1537, 1542 [criticizing comment k for lack of clarity].) This court has concluded that "in fact the principle it [comment k] states is based on negligence." (*Brown* v. *Superior Court, supra,* 44 Cal.3d at p. 1059.)

The negligence-based standard of comment k to section 402A of the Restatement Second of Torts
1123 reflects a recognition that imposing strict *1123
liability on manufacturers of prescription drugs would harm the public interest by discouraging the development and availability of medications that cure diseases, alleviate pain and suffering, or sustain life. In the words of Dean Prosser: "The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them." (Prosser, Torts (4th ed. 1971) § 99, p. 661, fns. omitted.)

This concern — not to impose an excessively broad standard of liability on prescription drug manufacturers — continues today. Thus, the current tentative draft of the Restatement Third of Torts contains a special section governing products liability for prescription drugs and medical devices. With regard to warning defects, section 8 provides: "(d) A prescription drug or medical device is not reasonably safe because of inadequate instructions or warnings when [¶] (1) reasonable instructions or warnings regarding foreseeable risks of harm posed by the drug or medical device are not provided to prescribing and other health care providers. . . ." (Rest.3d Torts: Products Liability (Tent. Draft No. 2, Mar. 13, 1995) § 8, p. 210.)[1]

[1] The tentative draft of the Restatement Third of Torts may be part of a general retrenchment of products liability law. As one commentator observes: "In the past decade, however, further judicial expansion of tort and products liability law largely has come to an end. `A new tort era' has been entered that has been marked by `the stabilization and contraction of [tort] doctrine,' rather than its growth and development. Judicial opinions in the products liability field reflect growing concerns that the liability system is affecting the costs and availability of products adversely." (Schwartz, *The Impact of the New Products Liability Restatement on Prescription Products* (1995) 50 Food Drug L.J. 399, 400, brackets in Schwartz, fns. omitted.)

This court has in recent years addressed liability for "warning defects" for products other than prescription drugs (*Anderson* v. *Owens-Corning Fiberglas Corp., supra,* 53 Cal.3d 987 [evidence of whether risk known or knowable admissible in failure-to-warn case not involving prescription drugs]) as well as liability for prescription drug "

design defects" (*Brown* v. *Superior Court, supra,* 44 Cal.3d 1049 [prescription drug manufacturers exempt from strict liability for design defect claims]). But this court has not previously defined the elements necessary to establish a drug manufacturer's liability for failure to warn of a risk presented by a prescription drug.

To summarize, products or strict liability law was developed to compensate consumers injured by defective products without so expanding liability as to discourage manufacturers from developing and marketing products beneficial to the public. General principles of products liability law appropriately accommodate these competing interests for most types of products. *1124 As will be seen, prescription drugs require a standard of liability and a burden-of-proof allocation somewhat different from those used for other products. In this case, neither the majority nor the dissent has adequately accommodated two different consumer interests at stake.

II.

At first glance, the majority's holding — that a prescription drug manufacturer need warn only of those risks that are "known or reasonably scientifically knowable" (maj. opn., *ante,* at p. 1109) — appears quite reasonable. A close look, however, reveals that the majority imposes on a manufacturer a duty to warn of any risk that arguably may exist. The sheer breadth of that duty threatens two fundamental public interests. First, the majority's holding will result in the problems of overwarning this court has previously recognized, thereby undermining the public interest in consumer protection. Second, by subjecting prescription drug manufacturers to excessive liability, the majority's standard jeopardizes the important public interest of encouraging the development, availability, and affordability of beneficial prescription drugs.

To discern what the majority means by the phrase "known or reasonably scientifically knowable" is no easy task. Throughout its opinion, the majority itself gives different descriptions of the meaning of that phrase (see maj. opn., *ante,* at p. 1108 ["known to the scientific community"]; *id*. at p. 1112 ["`generally recognized and prevailing best scientific and medical knowledge available'"]; *id*. at p. 1113, fn. 3 ["knowledge obtainable `"by the application of reasonable, developed human skill and foresight"'"]; *ibid*. ["`true choice judgment'"]; *id*. at p. 1115 ["reasonable scientist operating in good faith should have known under the circumstances of the evidence"]; *id*. at p. 1116 ["evidence established a casual link between an alleged side effect and a prescription drug"]; *ibid*. ["knowable by the application of scientific and medical knowledge available"]).

The majority's various characterizations of "knowability" lead me to conclude that the majority considers a risk to be "knowable," even though not actually known to the manufacturer, if the risk at the time of distribution had been or reasonably could have been scientifically identified. The word "risk" simply means the possibility of a loss. (Webster's New Collegiate Dict. (9th ed. 1988) p. 1018, col. 1.) Because the majority does not suggest that the degree of probability of loss is of any significance, the majority seemingly equates the identification of a bare possibility of harm with "knowability" and hence a duty to warn. Thus, under the majority's holding, once a prescription drug plaintiff proves that a risk has been or reasonably *1125 could have been identified by the scientific community, the manufacturer has a duty to warn regardless of whether warning is otherwise appropriate or reasonable.[2]

[2] On page 1116 of its opinion, the majority states: "The application of the failure-to-warn theory to pharmaceuticals requires determinations whether available evidence established a causal link between an alleged side effect and a prescription drug, *whether any warning should have been given,* and, if so, whether the warning was adequate. These are issues of fact involving, inter alia, questions concerning

> the state of the art, i.e., what was known or reasonably knowable by the application of scientific and medical knowledge available at the time of manufacture and distribution of the prescription drug. They also necessarily involve questions concerning whether the risk, in light of accepted scientific norms, was more than merely speculative or conjectural, *or so remote and insignificant as to be negligible*." (Italics added.) These statements only further obscure what the majority means by the phrase "known or reasonably scientifically knowable." The italicized portions of the sentences quoted above are either yet another way of expressing the majority's "knowability" standard that the duty to warn does not extend to unknowable risks or a concession that the standard of liability includes reasonableness of the manufacturer's conduct. (But see maj. opn., *ante,* at p. 1112 ["`the reasonableness of the defendant's failure to warn is immaterial'"].)

The majority insists that its conclusion is dictated by our decisions in *Brown* v. *Superior Court, supra,* 44 Cal.3d 1049, and *Anderson* v. *Owens-Corning Fiberglas Corp., supra,* 53 Cal.3d 987. (Maj. opn., *ante,* at pp. 1108-1109, 1116-1117.) But, as Justice Baxter convincingly demonstrates in his dissent, the majority is wrong. (Dis. opn. of Baxter, J., *post,* at pp. 1153-1158.) This court has not previously decided this issue.

In my view, the majority's holding goes too far in imposing liability, because it fails to recognize the complexity involved in scientifically identifying a risk as meaningful and in determining whether a warning is appropriate. As this court has noted, the quality of scientific evidence "may range from extremely vague to highly certain." (*Finn* v. *G.D. Searle Co*. (1984) 35 Cal.3d 691, 701 [200 Cal.Rptr. 870, 677 P.2d 1147].) Scientific studies suggesting associations between products and injuries may themselves be subjected to legitimate question as to the validity of their methods and the soundness of their conclusions. (See *Ramirez* v. *Plough, Inc*. (1993) 6 Cal.4th 539, 556 [25 Cal.Rptr.2d 97, 863 P.2d 167, 27 A.L.R.5th 899] [explaining that in 1986, methodology of scientific studies showing an association between aspirin and Reye's syndrome had been questioned, and the Food and Drug Administration had determined that further studies to confirm or disprove association were necessary]; see generally, Foster et al., Phantom Risk: Scientific Inference and the Law (1993).) The majority's apparent standard that a prescription drug manufacturer is strictly liable for failure to warn of any "knowable" risk fails to recognize, much less deal with, the complexity of scientific evaluations.

A possible result of such a standard is the destruction of the viability of any warnings. " [B]oth common sense and experience suggest that 1126 if every *1126 report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given. [Citations.] The strength of the causal link thus is relevant both to the issue of whether a warning should be given at all, and, if one is required, what form it should take." (*Finn* v. *G.D. Searle Co., supra,* 35 Cal.3d at p. 701.) Too broad a standard may prove ineffective and even counterproductive. (See *Ramirez* v. *Plough, Inc., supra,* 6 Cal. 4th at p. 553; Twerski et al., *The Use and Abuse of Warnings in Products Liability — Design Defect Litigation Comes of Age* (1976) 61 Cornell L.Rev. 495, 513-517; Prosser Keeton on Torts, *supra,* § 96, p. 686 ["Too much detail can be counterproductive. A warning to be effective must be read and understood."].)

The problems of overwarning are exacerbated if warnings must be given even as to very remote risks, which drug manufacturers may find necessary under the vague standard that the majority adopts today. "Not only would such

remote risk warnings crowd out potentially useful warnings but they would also focus consumer attention on the fairy tale bogeyman. One cannot cry wolf without paying the price over the long term." (Henderson Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn* (1990) 65 N.Y.U.L.Rev. 265, 318.)

According to the majority, its standard of liability would not result in inundating consumers with too many warnings, because the manufacturer's duty to warn runs to the physician rather than the patient, and because there is no duty to warn of obvious dangers. (Maj. opn., *ante,* at p. 1116.)

It is true, as the majority states, that a prescription drug manufacturer has no duty to ensure that a warning given a physician reaches the patient. (*Stevens* v. *Parke, Davis Co*. (1973) 9 Cal.3d 51, 65 [107 Cal.Rptr. 45, 507 P.2d 653, 94 A.L.R.3d 1059].) But even physicians, the "learned intermediaries," may be overwhelmed by excessive warnings. As this court has recognized, both common sense and experience suggest that to require a manufacturer "to inundate physicians indiscriminately with notice of any and every hint of danger" inevitably dilutes "the force of any specific warning given." (*Finn* v. *G.D. Searle Co., supra,* 35 Cal.3d at p. 701; contra, maj. opn., *ante,* at p. 1116, fn. 6.) And, contrary to the majority's assertion, the absence of a duty to warn of known or obvious dangers has little import in the context of prescription drugs, because few of the sophisticated potential risks of prescription drugs could be considered obvious.

The majority's holding exposes prescription drug manufacturers to such broad liability that they may restrict or cease the development and distribution of life-sustaining and lifesaving drugs, 1127 thereby defeating a strong public *1127 interest. As this court has observed: "[T]here is an important distinction between prescription drugs and other products such as construction machinery [citations], a lawnmower [citation], or perfume [citation], the producers of which were held strictly liable. In the latter cases, the product is used to make work easier or to provide pleasure, while in the former it may be necessary to alleviate pain and suffering or to sustain life. Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable. *Because of these distinctions, the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use*." (*Brown* v. *Superior Court, supra,* 44 Cal.3d at p. 1063, italics added.) This distinction between prescription drugs and other products, the legal significance of which the majority denies (see maj. opn., *ante,* at p. 1116, fn. 5), is firmly rooted in products liability law and was the basis for this court's unanimous decision in *Brown* v. *Superior Court, supra,* at pages 1063-1065.[3]

[3] In footnote 5 at page 1116 of its opinion, the majority characterizes my view as suggesting that the "costs" of prescription drug liability have been excessive and then asserts that it is unclear how my approach would reduce "those costs — unless the inevitable result would be to deprive an innocent injured person of any remedy." It is true that under my approach not every person injured by the side effects of a prescription drug would recover. But limiting somewhat the scope of liability for failure to warn of risks associated with prescription drugs, as I would do, will best assure that millions of other innocent people — those suffering from debilitating or even fatal diseases — will have available to them prescription drugs that sustain life or health. Moreover, in requiring the plaintiff to prove that the risk was known or reasonably scientifically knowable, the majority's holding too will "deprive an innocent injured person of any remedy."

The concern repeatedly voiced by the courts and legal commentators that the imposition of excessive liability on prescription drug manufacturers may discourage the development and availability of life-sustaining and lifesaving drugs is well founded, as the following discussion demonstrates.

In 1976, because the threat of excessive tort liability was deterring drug manufacturers from developing a vaccine for swine flu needed to protect public health, Congress enacted the Swine Flu Act, under which the federal government assumed the risk of lawsuits arising from injuries associated with the vaccine. (Pub.L. No. 94-380 (Aug. 12, 1976) § 2, 90 Stat. 1113; Franklin Mais, *Tort Law and Mass. Immunization Programs: Lessons from the Polio and Flu Episodes* (1977) 65 Cal.L.Rev. 754, 769; see *Brown* v. *Superior Court, supra,* 44 Cal.3d at p. 1064.)

In 1983, Benedictin, the only antinauseant drug available to pregnant women, was withdrawn from the market because the cost of insurance almost consumed the entire income from the sale of the
1128 drug and its price *1128 had already increased by over 300 percent. (*Brown* v. *Superior Court, supra,* 44 Cal.3d at p. 1064.)

In the mid-1980's, a producer of the diphtheria-pertussis-tetanus (DPT) vaccine withdrew its product from the market because of "extreme liability exposure, costs of litigation and the difficulty of continuing to obtain adequate insurance." (*Brown* v. *Superior Court, supra,* 44 Cal.3d at p. 1064, quoting Hearing on Vaccine Injury Compensation Before Subcom. on Health and the Environment of House Com. on Energy and Commerce, 98th Cong., 2d Sess. (Sept. 10, 1984) p. 295.) By 1986, there were only two manufacturers of the DPT vaccine still marketing the drug and its costs had risen from 11 cents per dose in 1982 to $11.40 per dose in 1986, $8 of which was for insurance reserves. (*Brown* v. *Superior Court, supra,* 44 Cal.3d at p. 1064.) Incidentally, that same year the unavailability of insurance prevented a manufacturer from marketing a new drug to treat vision problems. (*Id*. at p. 1065.)

In 1990, it was reported that the threat of products liability litigation had left the United States with just one manufacturer of the polio vaccine and one manufacturer of the combined measles, mumps and rubella vaccine. (Remarks of Sen. Heinz, 136 Cong. Rec. S16661, S16662 (Oct. 25, 1990).)

More recently, the imposition of too harsh a standard for products liability on manufacturers of prescription drugs has been mentioned as a possible impediment to this country's ability to combat the serious public health threat posed by Acquired Immune Deficiency Syndrome (AIDS). (See generally, Arnold, *Developing, Testing, and Marketing an AIDS Vaccine: Legal Concerns for Manufacturers* (1991) 139 U. Pa. L.Rev. 1077.)

To require prescription drug manufacturers to warn of all scientifically knowable risks, as the majority holds, exposes them to excessive liability. Such exposure creates a powerful disincentive on the part of prescription drug manufacturers to develop essential medications, especially when it is joined with the extensive liability exposure for alleged inadequacy of warnings given. (See, e.g., *MacDonald* v. *Ortho Pharmaceutical Corp*. (1985) 394 Mass. 131 [475 N.E.2d 65, 71] [adequacy of warning that use of oral contraceptive may cause abnormal blood clotting in such vital organs as the brain and that the abnormal clotting may be fatal presented question of fact because it did not use the word "stroke"]; see also Henderson Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, supra,* 65 N.Y.U.L.Rev. at pp. 318-319.)

In short, the broad standard of liability to which the majority subjects manufacturers of prescription drugs may cause manufacturers to
1129 issue so *1129 many warnings that the effectiveness of the most important warnings will

be negated, and it jeopardizes the vital public interest in the development and availability of life- and health-sustaining drugs.

Although the latter interest is advanced by the dissent's proposed rule, the dissent's approach places too heavy a burden on the injured consumer.

III.

Justice Baxter's dissent expresses the view that a prescription drug manufacturer's liability for failure to warn should be based solely upon negligence principles. Under that approach, a manufacturer is liable for failure to warn only if the plaintiff establishes that a reasonable manufacturer in similar circumstances would have issued warnings. (Dis. opn. of Baxter, J., *post,* at pp. 1147, 1162; see 6 Witkin, Summary of Cal. Law (9th ed. 1988) Torts, § 729, pp. 56-58.)

The dissent agrees with the majority that the legal theories of negligent failure to warn and strict liability failure to warn are two different theories of liability: negligence looks to the reasonableness of a manufacturer's conduct while strict liability considers it irrelevant. (Dis. opn. of Baxter, J., *post,* at pp. 1157-1158.) According to the dissent, the same policy considerations that led this court in *Brown* v. *Superior Court, supra,* 44 Cal.3d 1049, to adopt a negligence standard for prescription drug design defects apply with equal force when, as here, the alleged defect is a failure to warn of risks associated with the drug. (Dis. opn., *post,* at p. 1158.)

The dissent cites four reasons for its conclusion. First, it mentions that several commentators have concluded that a product's warning may be characterized as a subset of the product's design. (Dis. opn. of Baxter, J., *post,* at p. 1158.) Second, the dissent points out that products liability law has always recognized that prescription drugs may require different legal treatment than other products, and that the tentative draft of the Restatement Third of Torts incorporates negligence principles into its new standard for prescription drug manufacturer products liability. (Dis. opn., *post,* at pp. 1159-1160.) Third, it notes that the prescription drug industry is heavily regulated by the federal Food and Drug Administration (FDA), and that one of the FDA's primary functions is to evaluate drug warnings. (*Id*. at pp. 1160-1161.) Fourth, the dissent points out that the imposition of strict liability for failure to warn on prescription drug manufacturers would inhibit and delay the development and marketing of essential drugs. (*Id*. at p. 1162.)

The negligence standard advocated by the dissent preserves the public interest in the development and availability of life-sustaining and lifesaving 1130*1130 drugs because prescription drug manufacturers would be liable only if their decision not to warn was unreasonable. But the dissent's approach would unnecessarily weaken the legal protection afforded injured consumers under products liability law.

As mentioned at the outset, a principal objective of products liability law is to relieve injured consumers of the problems of proof inherent in negligence and contractual warranty, common law concepts that were initially applied to consumers injured by defective products. (*Ante,* at pp. 1119-1120.) The dissent's approach runs counter to this important goal.

To prove a prescription drug manufacturer was negligent in failing to warn, an injured consumer would have to establish not only that the risk was scientifically appreciable and valid, but also, for example, that the risk was of sufficient magnitude in relation to other risks as to render it unreasonable not to warn, that the risk was not too remote, and that under all of the circumstances a prudent manufacturer would have issued a warning. Thus, the consumer would have to show not only that the risk at issue was scientifically credible, but also that its relative severity and probability in relation to other scientifically credible risks made the decision not to warn unreasonable.

Having developed and manufactured the product that injured the consumer, the manufacturer rather than the consumer is the one with superior access to the pertinent scientific data. Yet, the negligence standard proposed by the dissent would saddle the consumer with the burden of obtaining and evaluating the relevant scientific information.

In addition, under the dissent's approach, the injured consumer would have to prove that at the time of distribution there were no other factors that would make the manufacturer's decision not to warn reasonable. The other factors would involve "a balancing of the seriousness of the harm, the probability that the harm will result, and the burden involved in taking the necessary precautions." (Note, *Formulating the Strict Liability Failure to Warn* (1992) 49 Wn. Lee L.Rev. 1509, 1512, fn. omitted.) A manufacturer that is charged with possessing the requisite scientific information, that is in the business of developing and marketing prescription drugs, and that deals directly and on an ongoing basis with the FDA in evaluating the propriety and extent of warnings (see, e.g., 21 C.F.R. § 201.57 (1996), 310 et seq. (1995), 312 et seq. (1995), 314 et seq. (1995)), is far better situated to address the issues relating to the reasonableness of a decision whether to warn of a particular risk. An injured consumer, by comparison, does not have direct access to the relevant information and cannot reasonably be *1131 expected to have the resources necessary to satisfy the burden of proving negligence.

Accordingly, in my view, adoption of a negligence standard, as the dissent advocates, undermines the consumer protection goals underlying products liability law.

IV.

As explained above, there are serious drawbacks to the majority's strict liability standard and the dissent's negligence approach. Imposition of strict liability on prescription drug manufacturers may curtail the development of drugs beneficial to society, substantially increase the cost to the manufacturer and consequently the price charged to the consumer, and lead to the issuance of so many warnings as to negate their effectiveness. The dissent, on the other hand, by requiring an injured consumer to prove that a manufacturer's failure to warn was negligent or unreasonable, would saddle the consumer with an impossibly high burden of proof. In short, the majority's strict liability standard is too harsh towards the manufacturer of prescription drugs, while the dissent is too harsh towards the injured consumer.

I propose an intermediate approach, one that fairly accommodates the competing public policies. (See Schwartz, *Prescription Products and the Proposed Restatement (Third)* 61 Tenn. L.Rev. 1357, 1359 [pharmaceutical product's ability to reduce pain, save lives, and restore health should be balanced with its potential for producing serious injuries].) Unlike the majority, I would not impose liability on prescription drug manufacturers for their failure to warn of every arguable risk, but only of those risks supported by credible scientific evidence or that upon reasonable inquiry would be supported by credible scientific evidence. Unlike the dissent, I would not require the plaintiff consumer to show as part of the plaintiff's case that the manufacturer acted unreasonably; instead, I would allocate to the manufacturer the burden of proving that its decision not to warn was reasonable.

As I discussed earlier, there are two competing public policies at stake, each advancing a distinct and important consumer interest. On the one side, there are the interests that gave rise to the development of products liability law: to compensate consumers injured by deficient products and to encourage manufacturers to increase product safety. On the other side, there is society's interest in affordable prescription drugs, many of which are life sustaining and lifesaving. The majority's holding partially serves the first of these public policies by imposing a broad standard of liability, but it does so by jeopardizing the

effectiveness of the warnings given and by undermining *1132 the public interest in ensuring the development and availability of beneficial drugs. Although the dissent advances the latter policy, it weakens the protection of injured consumers by imposing on them too onerous a burden of proof. Thus, both the majority and the dissent sacrifice an important policy to the detriment of another equally important policy.

A balance of these important public policies may be achieved by a hybrid or intermediate approach that borrows the best features from strict liability as well as negligence. This approach has two steps: (1) The plaintiff would have the burden of establishing a prima facie case by proving that, at the time of distribution of the drug, scientifically credible evidence had identified the risk, or that upon reasonable inquiry the risk would have been identified by scientifically credible evidence; (2) then the burden of proof would shift to the manufacturer to show that its decision not to warn was reasonable.

As to the first step, I find guidance in previous decisions of this court. In determining the admissibility of new scientific techniques, this court has held that evidence of a technique is admissible only if it has gained acceptance in the particular scientific field to which it belongs. (*People* v. *Kelly* (1976) 17 Cal.3d 24, 30 [130 Cal.Rptr. 144, 549 P.2d 1240] [voiceprint analysis].) Acceptance of the technique for purposes of admissibility is established if the proponent of the evidence shows that a cross-section of the relevant scientific community accepts the technique as scientifically credible. (See *People* v. *Leahy* (1994) 8 Cal.4th 587, 612 [34 Cal.Rptr.2d 663, 882 P.2d 321] [horizontal gaze nystagmus]; *People* v. *Shirley* (1982) 31 Cal.3d 18, 56 [181 Cal.Rptr. 243, 723 P.2d 1354] [pretrial hypnosis of witnesses].) Acceptance does not require numerical majority support; in determining whether a technique has attained the requisite acceptance, both the quality and the quantity of the supporting and opposing evidence must be considered. (*People* v. *Leahy, supra,* at p. 612.)

Similarly, I would require the plaintiff in a prescription drug case to show that at the time of the manufacturer's distribution of the drug evidence of a risk of harm from the drug was considered credible in the relevant scientific community or that a reasonable scientist would have investigated the possibility of a risk and the investigation would have resulted in scientifically credible evidence of the risk's existence. Evidence of a risk would be scientifically credible if the data upon which it is based, the methodology employed, and its conclusions identifying the existence of a risk comply *1133 with generally accepted scientific methodology and analysis.[4] Scientific evidence that postulates the possibility of a risk or that is otherwise speculative or conjectural would be inadequate. Also, the relevant inquiry relates to the credibility of the scientific evidence in light of accepted scientific norms, not to the personal professional beliefs or preferences of an otherwise qualified expert.

[4] A manufacturer may have a duty to warn even in the absence of credible scientific evidence as defined here if the plaintiff can establish that a reasonable manufacturer would have warned.

The plaintiff's identification of such a risk would not by itself subject the manufacturer to liability for failure to warn of the risk associated with the drug prescribed. Against the benefits that may be gained by a warning must be balanced the dangers of overwarning and of less meaningful warnings crowding out necessary warnings, the problems of remote risks, and the seriousness of the possible harm to the consumer. But requiring a plaintiff to prove that these factors supported the giving of a warning would force the plaintiff to independently obtain and evaluate all relevant scientific information bearing on these factors. Because such information is not readily accessible to plaintiffs, who may also lack the resources

necessary to analyze and evaluate the information, it would impose too heavy a burden on plaintiffs to require them to prove that a warning should have been given because of factors such as the magnitude of the risk in relation to other risks, the seriousness of the harm, and the probability of the harm. Therefore, I would shift to the manufacturer the burden of proving justification for the failure to warn of the risk established by the consumer's prima facie case. (See Evid. Code, §§ 605, 606.)

To satisfy its burden, the manufacturer would have to show that its failure to warn was reasonable in relation to the identified risk. The manufacturer, for instance, could introduce evidence that the risk did not pose a serious threat to health, that it was remote, that the number or relative severity of other risks justified a failure to warn, or that the scientific association between the drug and the risk was weak. The manufacturer's compliance with product safety statutes or regulations such as those of the FDA would also be relevant, but not necessarily controlling.[5] The same is true of industry standards and practices to the extent they relate to the reasonableness of the manufacturer's decision not to warn. (See Prosser Keeton on 1134 Torts, *supra,* § 33, pp. 193-196.) *1134

[5] I agree with the majority that a prescription drug manufacturer cannot be held liable for failure to warn if it was precluded from issuing a warning by the FDA. (Maj. opn., *ante,* at p. 1115 fn. 4.) A contrary conclusion would be unreasonable because it would make manufacturer compliance with both federal and state laws impossible. I also agree with the majority that FDA regulations and action or inaction would be admissible as probative of whether a manufacturer should have warned of a risk. (*Id.* at p. 1114.)

In my view, this allocation of the burden of proof is appropriate given the manufacturer's superior access to and capability of evaluating the relevant scientific information; it also furthers a goal of products liability law of relieving injured consumers from evidentiary burdens that may be too onerous. (See *Barker* v. *Lull Engineering Co., supra,* 20 Cal. 3d at p. 431 [holding that once a plaintiff makes a prima facie showing of injury caused by product's design, the burden should shift to the defendant to prove that the product is not defective].)

Is this solution perfect? Perhaps not. But it does attempt to strike a fair balance between two distinct public interests: compensating consumers injured by defective products, and encouraging the development of prescription drugs, many of which are life sustaining and lifesaving.

I now turn to the facts of this case.

V.

Here, plaintiff Wilma Peggy Carlin sued defendant the Upjohn Company, among others, for injuries allegedly caused by taking Halcion, a drug manufactured by defendant and prescribed by plaintiff's physician. Plaintiff alleges that Halcion is intended for the treatment of, among other things, insomnia, and that she ingested the drug from 1987 through November 1992. She asserts that Halcion caused her emotional, physical, and psychic injuries, and that defendant knew or should have known that the drug could cause these injuries.

The complaint attempts to state causes of action for strict liability for failure to properly prepare and warn of the dangerous propensities of Halcion, negligence, breach of warranty, failure to warn, and fraud. Citing *Brown* v. *Superior Court, supra,* 44 Cal.3d 1049, defendant manufacturer demurred to the causes of action for strict liability and breach of warranty, arguing that such causes of action cannot be maintained against a prescription drug manufacturer. The trial court sustained defendant's demurrer without leave to amend to the causes of action for strict liability and breach of warranty. Thereafter, the Court of Appeal granted plaintiff's petition for a writ of mandate and directed the trial court to overrule the demurrer, citing this court's decision in *Anderson*

v. *Owens-Corning Fiberglas Corp., supra,* 53 Cal.3d 987, as permitting a plaintiff in a prescription drug manufacturer case to maintain a cause of action in strict liability for a failure to warn of a known or knowable risk.

Although plaintiff's cause of action is more properly termed "products liability for failure to warn," her complaint contains allegations 1135 sufficient to *1135 withstand a demurrer. Under applicable law, a demurrer may not be sustained if the complaint states facts sufficient to constitute a cause of action. (See, e.g., *Blank* v. *Kirwan* (1985) 39 Cal.3d 311, 318 [216 Cal.Rptr. 718, 703 P.2d 58].) Here, plaintiff alleged that defendant manufacturer knew or should have known of Halcion's dangerous propensities at the time of its distribution. These allegations are sufficient to state a prima facie case.

CONCLUSION

The continuing debate over the proper standard of liability for prescription drug warning defects has largely been framed as though the only available alternatives were strict liability and negligence. Both the majority and the dissent in this case address the issue from within that limited framework. For the reasons stated above, however, I am convinced that the framework must be discarded in order to craft a standard of liability that achieves a just resolution of competing public policies.

My approach favors neither party at the expense of the other, as the majority and the dissent do. Instead, my approach seeks to strike a balance between two quite distinct consumer interests: providing compensation to the injured consumer, and encouraging the development and availability of affordable health- and life-sustaining prescription drugs.

Although I disagree with the majority's standard of liability, I join the majority's disposition affirming the judgment of the Court of Appeal, which directs the trial court to vacate its order sustaining the demurrer and to enter a new order overruling the demurrer.

TURNER, J.,[fn*] Concurring and Dissenting. [fn*] Presiding Justice, Court of Appeal, Second Appellate District, Division Five, assigned by the Acting Chief Justice pursuant to article VI, section 6 of the California Constitution.

This case involves the efforts of seven justices to faithfully apply the holding of *Brown* v. *Superior Court* (1988) 44 Cal.3d 1049 [245 Cal.Rptr. 412, 751 P.2d 470] (*Brown,* hereafter) to the first amended complaint of plaintiff, Wilma Peggy Carlin, which alleges defendant, the Upjohn Company, failed to warn her of a known or knowable risk concerning the drug Halcion. The four opinions filed in this matter involve an effort to apply *Brown* to the present case in light of considerations which have come to light since Justice Mosk, with the concurrence of six other justices, applied a modified form of failure to warn strict tort liability principles to prescription drugs in 1988. I agree with the majority plaintiff has stated a cause of action for a failure to warn of a known risk of Halcion, the drug in question. I further agree that the cause is action for failure to warn is different from a negligence claim. In that 1136 *1136 respect, I respectfully disagree with Justice Baxter's analysis that plaintiff's failure to warn of a known risk cause of action is merely a negligence claim. My disagreement with the majority is that the failure to warn of a known risk theory is not really a cause of action in strict liability for reasons that will be explained. Rather, a cause action for failure to disclose to a physician a known adverse side effect of a prescription drug results in heightened risk of potential responsibility but does not, given the decisions of the courts of this state, give rise to what has commonly been described as strict tort liability. I am in complete agreement with Justice Baxter, though, insofar as he concludes that a failure to

warn of a knowable risk is subject to traditional negligence principles including the unavailability of punitive damages.

I. KNOWN RISKS

There are two reasons why the failure of a drug manufacturer ought to be viewed as something other than strict liability. First, the historical purposes of strict tort liability have only limited application to a failure to warn in the drug manufacturer context. Second, because of the inclusion of negligence concepts in a failure to warn case, there is no longer anything "strict" about the liability a drug manufacturer is subject to when it fails to advise a tort plaintiff's physician about the adverse side effects of a prescription drug.

A. *The Historical Purposes of Strict Tort Liability and Their Limited Applicability to Failure to Warn of Known Defect Cases*

The doctrine of strict liability has its origins in the concurring opinion of then Associate Justice Traynor in *Escola* v. *Coca Cola Bottling Co*. (1944) 24 Cal.2d 453, 461 [150 P.2d 436] in which he advocated subjecting a manufacturer to "absolute liability" when "an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings." This court adopted Justice Traynor's position, without the "absolute liability" language, in *Greenman* v. *Yuba Power Products, Inc*. (1963) 59 Cal.2d 57, 62 [27 Cal.Rptr. 697, 377 P.2d 897, 13 A.L.R.3d 1049], wherein it was stated: "A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." The purpose of the doctrine of strict liability was "to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves." (*Id*. at p. 63.) The doctrine also served "to relieve an injured plaintiff of many of the onerous evidentiary burdens inherent in a negligence cause of action." (*Barker* v. *Lull* 1137 *Engineering Co*. (1978) 20 Cal.3d 413, 431 *1137 [143 Cal.Rptr. 225, 573 P.2d 443, 96 A.L.R.3d 1].) *Daly* v. *General Motors Corp*. (1978) 20 Cal.3d 725, 733 [144 Cal.Rptr. 380, 575 P.2d 1162] noted that the term "strict liability" was not the equivalent of "absolute liability." In *Daly,* this court held: "From its inception, however, strict liability has never been, and is not now, *absolute* liability. As has been repeatedly expressed, under strict liability the manufacturer does not thereby become the insurer of the safety of the product's user. [Citations.]" (*Ibid.,* original italics.)

As noted by the majority, there are three types of potential strict tort liability. In *Anderson* v. *Owens-Corning Fiberglas Corp*. (1991) 53 Cal.3d 987, 995 [281 Cal.Rptr. 528, 810 P.2d 549] (*Anderson,* hereafter), Associate Justice Panelli noted, "Strict liability has been invoked for three types of defects — manufacturing defects, design defects, and `warning defects,' i.e., inadequate warnings or failures to warn." This appeal arises in the latter type of defect, failure to warn specifically with regard to a prescription drug. It had been held that when a drug is placed upon the market and sold without adequate and proper warning of a known risk, a manufacturer may be "strictly liable" for resulting injury. (*Toole* v. *Richardson-Merrell Inc*. (1967) 251 Cal.App.2d 689, 711 [60 Cal.Rptr. 398, 29 A.L.R.3d 988]; see also *Carmichael* v. *Reitz* (1971) 17 Cal.App.3d 958, 988 [95 Cal.Rptr. 381]; Rest.2d Torts, § 402A, com. k, pp. 353-354.) In *Brown,* this court held in the prescription drug context, there was no strict tort liability when the risk was unknowable; rather liability only arose if the risk was "known or reasonably scientifically knowable at the time of distribution." (*Brown, supra,* 44 Cal.3d at p. 1069, fn. omitted.) In *Anderson,* this court noted that the theory of strict liability for failure to warn had been principally developed in the Courts of

Appeal culminating in the principle that "a failure to give adequate warnings might subject a manufacturer or distributor to *strict liability* when it knew or should have known of the danger and the necessity of warnings to ensure safe use." (*Anderson, supra,* 53 Cal.3d at p. 996, original italics, and cases cited therein.) *Anderson* noted that in the previous Court of Appeal decisions that: the Courts of Appeal had not focused on the factual question of whether a manufacturer knew or should have known of the risks involved in the products, because of the nature of the product or risk made such discussion unnecessary; the issue of whether the manufacturer knew or should have known was not at issue in those cases because plaintiffs had limited the action to risks which were obviously known or should have been known; and despite the failure of the Courts of Appeal to discuss the issue knowledge or knowability, such was an implicit condition of strict liability. According to *Anderson* the knowledge aspect was only the focus as a component of failure to warn when the issue was whether the danger to be warned against was "unknowable." In such cases, the consensus was
1138 that knowledge or *1138 knowability was a factor in the obligation to warn under section 402A, comment j of the Restatement Second of Torts, because eliminating the knowledge component would have the effect of turning strict liability into absolute financial responsibility. (*Anderson, supra,* 53 Cal.3d at pp. 997-998, citing *Oakes* v. *E.I. Du Pont de Nemours Co., Inc*. (1969) 272 Cal.App.2d 645, 650-651 [77 Cal.Rptr. 709] and *Christofferson* v. *Kaiser Foundation Hospitals* (1971) 15 Cal.App.3d 75, 79 [92 Cal.Rptr. 825, 53 A.L.R.3d 292].) I agree with the majority the failure of a drug manufacturer to warn of a known risk gives rise to potential liability. The foregoing authority clearly so holds. Stare decisis concerns, the need for predictability in the law, and the subtle yet distinct manner in which negligence is different from failure to warn in the drug context warrant acceptance of this now well-established principle. Any change should come from the Legislature. However, in my view, I conclude that in the case of a failure to warn of a known risk of a side effect of a prescription drug by a manufacturer, it is both confusing and unnecessary to continue to apply the label of "strict liability."

First, neither of the purposes of imposing strict liability on a prescription drug manufacturer is being served when the issue is a known risk. As noted above, a key purpose of the doctrine of strict liability is "to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves." (*Greenman* v. *Yuba Power Products, Inc., supra,* 59 Cal.2d at p. 63.) *Brown* noted generally: "[T]he fundamental reasons underlying the imposition of strict liability are to deter manufacturers from marketing products that are unsafe, and to spread the cost of injury from the plaintiff to the consuming public, which will pay a higher price for the product to reflect the increased expense of insurance to the manufacturer resulting from its greater exposure to liability." (44 Cal.3d at pp. 1062-1063.) *Brown* also rejected the imposition of strict liability against the manufacturers of prescription drugs for design defects and failure to warn of unknown risks, on public interest grounds. In exempting prescription drug manufactures from strict liability principles under such circumstances, *Brown* stated: "It is indisputable, . . . that the risk of injury from such drugs is unavoidable, that a consumer may be helpless to protect himself from serious harm caused by them, and that, like other products, the cost of insuring against strict liability can be passed on by the producer to the consumer who buys the item. Moreover, . . . in some cases additional testing of drugs before they are marketed might reveal dangerous side effects, resulting in a safer product. [¶] But there is an important distinction between prescription drugs and other products such as construction machinery [citations], a lawnmower [citation], or perfume [citation], the producers of which were held

1139 strictly liable. In the latter cases, *1139 the product is used to make work easier or to provide pleasure, while in the former it may be necessary to alleviate pain and suffering or to sustain life. Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable. Because of these distinctions, the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use. [¶] Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases such a delay in marketing new drugs — added to the delay required to obtain approval for release of the product from the Food and Drug Administration — would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering. [¶] If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability — assuming insurance would be available — and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most." (*Brown, supra,* at p. 1063.) This court, by exempting prescription drug manufacturers from strict liability under such circumstances and thereby refusing to "pre-allocate" the burden of the costs on the manufacturers of prescription, indicates it has determined that the benefits to society from prescription drugs did not warrant the imposition of a doctrine of strict liability. Strict liability of necessity preallocated the burden of the costs to the manufacturer rather than the consumer, even when the risk was known or unknown.

Second, by requiring the plaintiff to prove what the defendant knew, i.e., focusing on the defendant's conduct, the second primary purpose of the doctrine, which is "to relieve an injured plaintiff of many of the onerous evidentiary burdens inherent in a negligence cause of action" (*Barker* v. *Lull Engineering Co., supra,* 20 Cal.3d at p. 431), has been largely defeated. In *Brown,* this court noted, "Strict liability differs from negligence in that it eliminates the necessity for the injured party to prove that the manufacturer of the product which caused injury was negligent. It focusses not on the conduct of the manufacturer but on the product itself, and holds the manufacturer liable if the product was defective." (*Brown, supra,* 44 Cal.3d at p. 1056.) Further, in *Brown,* the traditional failure to warn rule was identified as follows; "The test stated in comment 1140 k is to be distinguished from strict *1140 liability for failure to warn. Although both concepts identify failure to warn as the basis of liability, comment k imposes liability only if the manufacturer knew or should have known of the defect at the time the product was sold or distributed. Under strict liability, the reason why the warning was not issued is irrelevant, and the manufacturer is liable even if it neither knew nor could have known of the defect about which the warning was required. Thus, comment k, by [focusing] on the blameworthiness of the manufacturer, sets forth a test which sounds in negligence, while imposition of liability for failure to warn without regard to the reason for such failure is consistent with strict liability since it asks only whether the product that caused injury contained a defect. [Citation.]" (*Id.* at p. 1059, fn. 4.) As several courts have noted, where the issue is a known or knowable risk "`concepts from negligence law have been amalgamated into the doctrine of strict liability. . . .'" (*Finn* v. *G.D.*

Searle Co. (1984) 35 Cal.3d 691, 700 [200 Cal.Rptr. 870, 677 P.2d 1147], quoting *Carmichael* v. *Reitz, supra,* 17 Cal.App.3d at p. 988.) Under California law, the doctrine of strict liability relieved plaintiff from having to prove defendant's negligence in appropriate cases. (*Barker* v. *Lull Engineering Co., supra,* 20 Cal.3d at p. 431.) However, the practical effect of requiring plaintiff to prove that defendant acted in spite of a known risk, under a standard which everyone agrees is riddled with negligence concepts, is to heighten plaintiff's burden of proof in the failure to warn context. Further, unlike strict liability where the reason for the failure to warn is irrelevant, drug manufacturer responsibility is measured by what it knew and its blameworthiness for failing to have warned. (*Brown, supra,* 44 Cal. 3d at p. 1059.) Thus, the two fundamental policies behind the doctrine as set out in *Greenman* and its progeny are not being served. Continuing to adhere to the legal fiction that there is "strict liability" in failure to warn cases in the prescription drug context serves no purpose other than to add confusion to an already complex and obscure segment of the law.

It has been argued by a portion of the bar that *Anderson* and *Brown* may have contributed to the confusion in this area. What is clear from both these opinions is that contrary to defendants' position, and in accord with Justice Mosk's majority opinion in this case, at least in prescription drug failure to warn cases there is a "hybrid standard" which is neither strict liability nor ordinary negligence. The theory of failure to warn in the context of prescription drugs is not "strict liability" because it requires proof of defendant's conduct and requires an inquiry into what is known. After *Brown,* the focus is on what the manufacturer knew and when it knew it. In other words, unlike strict tort liability, the focus is in fact on the defendant's conduct.

In addition, as Justice Baxter points out, *Brown,* based on comment k to section 402A of the Restatement Second of Torts, recognized a public 1141 policy *1141 exception to strict liability for prescription drugs. However, liability is not measured by ordinary negligence standards. *Anderson* and *Brown* have made it clear that the infusion of negligence principles into failure to warn cases while modifying the very essence of the doctrine of strict liability did not completely erase the fundamental policies which were inherent in its creation. Stated another way, the infusion of negligence principles into failure to warn cases, which did not quite amount to "strict liability" but which was not as simple as "ordinary negligence," did not completely obliterate the policies behind maintaining a heightened standard of care for manufacturers of products with known risks (*Anderson, supra,* 53 Cal.3d at pp. 995-996 [asbestos manufacturer]) including prescription drug manufacturers. (*Brown, supra,* 44 Cal.3d at pp. 1069-1070 fn. 12.) A drug manufacturer does not escape all liability for defective drugs. As *Anderson* stated: "Our decision [in *Brown*] did not affect the continued validity . . . regarding liability for known and knowable risks. . . . `Our conclusion [in *Brown*] does not mean, of course, that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, as well as under general principles of negligence, *and* for failure to warn of known or reasonably knowable side effects.'" (*Anderson, supra,* at pp. 999-1000, original italics.) Accordingly, although not strict liability, defendant's potential responsibility should be measured by a standard other than negligence.

B. *The Non-strict Nature of Drug Manufacturer Liability for Failure to Warn of a Known Risk*

Whatever may have been the concept of strict tort liability at one time, the emergence of defenses and modifications to this area of law has made drug manufacturers anything other than strictly liable for failing to warn of a dangerous defect in a drug. The plaintiff's evidentiary burdens and available defenses render the failure to warn something other than a matter for which a

manufacturer may be strictly liable. For example, this court has recognized that if a strict tort liability plaintiff acted in a comparatively negligent fashion, the defendant's financial responsibility can be diminished. (*Safeway Stores, Inc*. v. *Nest-Kart* (1978) 21 Cal.3d 322, 325 [146 Cal.Rptr. 550, 579 P.2d 441]; *Daly* v. *General Motors Corp., supra,* 20 Cal. 3d at p. 742.) Furthermore, as the majority notes, if the Food and Drug Administration prohibits disclosure of even a known risk, there may be no strict tort liability.[1] (Maj. opn., *ante,* at pp. 1114-1115.) Moreover, if the known risk is remote, as the majority notes, there is no liability for failure to
1142 warn in the *1142 drug prescription context. As this court noted in *Finn* v. *G.D. Searle Co., supra,* 35 Cal.3d at page 701, "Moreover, both common sense and experience suggest that if every report of possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given." Given the foregoing limits on a drug manufacturer's liability for failure to warn of a known risk, the potential liability is not strict in my view. It can be characterized as a "hybrid" form of financial responsibility or perhaps "stricter" liability. But when all is said and done it is not "strict" liability.

[1] Insofar as the majority argues that a Food and Drug Administration prohibition against revealing a known or knowable risk is not a complete defense to a strict tort liability cause of action, I respectfully disagree. If a manufacturer is lawfully precluded by the government of the United States of America from advising of a risk, then California, a subordinate political entity, ought not punish by means of its tort liability laws a person or drug manufacturer that obeys federal law. This is not necessarily an issue of the supremacy clause (U.S. Const., art. VI, cl. 2), it is a commonsense rule California and any other state ought to follow in the development of its common law. In this respect, I agree with Justice Baxter.

C. *Conclusion Concerning Known Risk*

To sum up, I would suggest that the term "strict liability" does not accurately define the scenario where a drug manufacturer fails to warn of a known risk. This court's rule articulated in *Brown* and slightly modified today deviates from the nature of strict liability. Also, the rule for drug manufacturers contravenes the fundamental purposes of strict liability for the well-stated public policy reasons articulated in *Brown*. (*Brown, supra,* 44 Cal.3d at pp. 1063-1064.) Finally, this court's decisions have made it clear there is nothing strict about the liability of a drug manufacturer for failing to warn of a known risk. The test of liability is inextricably intertwined with negligence concepts. Although different from a negligence theory for the reasons expressed by the majority as well as in *Brown* and *Anderson,* drug manufacturer responsibility liability is no longer measured in terms of what is otherwise known as strict tort liability.

II. KNOWABLE RISKS

The fourth cause of action for failure to warn does not explicitly allege defendant neglected to advise plaintiff's physician of a knowable risk. The fourth cause of action alleges: "Plaintiff hereby incorporates herein as though again set forth in full, all of the allegations contained in paragraphs 1-14 of the General Allegations as well as paragraphs 15-34, and each of them, in the First, Second and Third Causes of Action. [¶] Defendants, and each of them, placed on the market and offered for sale the prescription drug *Halcion,* knowing that *Halcion* would be prescribed to health-care patients by their physicians, and that the drug would be used and/or relied upon by health-care patients, including
1143 plaintiff herein, as treatment for, amongst *1143

other things, insomnia. [¶] At all times alleged herein, *Halcion* was defective and/or unfit for its intended use in that *Halcion* was known to and did cause severe physical, mental and emotional damages/injuries to those health-care patients, including plaintiff herein, prescribed *Halcion* who took it for its intended purpose. [¶] Defendants, and each of them, failed to warn and/or adequately warn foreseeable health-care patients, and plaintiff herein, in particular, that *Halcion* was defective and/or unfit for its reasonably foreseeable use and that *Halcion* contained the dangerous propensities alleged herein." However, the fourth cause of action incorporates by reference the negligence claim. The negligence claim is in the second cause of action which contains allegations defendant negligently failed to advise plaintiff's physician of the probable adverse side effects of Halcion. Liberally construed, the fourth cause of action sufficiently alleges the second form of potential failure to warn liability — neglecting to advise plaintiff's physician of a knowable risk. (Code Civ. Proc., § 452;[2] *King* v. *Central Bank* (1977) 18 Cal.3d 840, 843 [135 Cal.Rptr. 771, 558 P.2d 857]; *Youngman* v. *Nevada Irrigation Dist*. (1969) 70 Cal.2d 240, 244-245 [74 Cal.Rptr. 398, 449 P.2d 462].)

[2] Code of Civil Procedure section 452 states: "In the construction of a pleading, for the purpose of determining its effect, its allegations must be liberally construed, with a view to substantial justice between the parties."

In *Brown,* this court described the test for drug manufacturer's test of liability for failure to warn of a knowable risk as follows: "They are subject to liability for manufacturing defects, as well as under general principles of negligence, and for failure to warn of known or *reasonably knowable side effects*." (*Brown, supra,* 44 Cal.3d at p. 1069, fn. 12, italics added.) *Anderson* used various terms for describing drug manufacturer liability for failing to advise a tort plaintiff's physician of a knowable adverse side effect of a prescription drug. *Anderson* used the following tests for describing manufacturer liability for failing to warn of a knowable risk: "constructive knowledge" in varying contexts (*Anderson, supra,* 53 Cal.3d at pp. 990, 999 fn. 12, 1000); "should have known of the risks" (*id*. at p. 997); "knowability" (*id*. at pp. 997 fn. 10, 999-1000, 1003); "ability to know" (*id*. at p. 998); "reasonably scientifically knowable" (*id*. at p. 999); and "`reasonably knowable side effects.'" (*Id*. at p. 1000.) *Anderson* excluded from the scope of strict tort liability failure to warn cases "scientifically unknowable dangerous propensities" (*id*. at p. 995) and utilized the word "unknowable" in several contexts. (*Id*. at pp. 998-999, 1002, 1003, fn. 14.) The foregoing language is also repeatedly utilized in varying forms by the majority in this case.

I disagree with plaintiff's argument that there is a meaningful distinction between the failure of a drug manufacturer to warn of a reasonably scientifically knowable risk, the test quite rightly articulated by the majority and *1144 established in 1144 *Brown, supra,* 44 Cal.3d at page 1069, footnote 12, and whether such neglect creates a situation where a reasonably prudent drug manufacturer has acted negligently. Stated differently, there is no meaningful distinction between plaintiff's failure to warn of a knowable risk and negligence theories. Further, the distinctions when presented to a jury are ephemeral and confusing. Hence, I would hold that the failure to warn of a knowable risk, as defined in *Brown,* is purely negligence.

The test of negligence was described by this court in *Flowers* v. *Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 997 [35 Cal.Rptr.2d 685, 884 P.2d 142] as follows: "`[N]egligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.' (Rest.2d Torts, § 282.) Thus, as a general proposition one `is required to exercise the care that a person of ordinary prudence would exercise under the circumstances.' [Citations.] Because application of

this principle is inherently situational, the amount of care deemed reasonable in any particular case will vary, while at the same time the standard of conduct itself remains constant, i.e., due care commensurate with the risk posed by the conduct taking into consideration all relevant circumstances. [Citations.]" (Fn. omitted.) In the past, this court has identified the relationship between reasonable conduct and liability of medical care professionals as follows: "Obviously we do not require that the therapist, in making that determination, render a perfect performance; the therapist need only exercise `that reasonable degree of skill, knowledge, and care ordinarily possessed and exercised by members of [that professional specialty] under similar circumstances.' [Citations.] Within the broad range of reasonable practice and treatment in which professional opinion and judgment may differ, the therapist is free to exercise his or her own best judgment without liability; proof, aided by hindsight, that he or she judged wrongly is insufficient to establish negligence." (*Tarasoff* v. *Regents of University of California* (1976) 17 Cal.3d 425, 438 [131 Cal.Rptr. 14, 551 P.2d 334, 83 A.L.R.3d 1166].) These principles of negligence which always involve an evaluation of the unreasonableness of the potential tortfeasor's conduct are well established tenets of California law. In *Crane* v. *Smith* (1943) 23 Cal.2d 288, 298 [144 P.2d 356], relying upon the Restatement First of Torts, this court held: "As in all cases where a standard of conduct is involved, the reasonable character of the care depends upon whether the interference with the actor's own affairs is warranted by the other's danger. The broad concept underlying the determination of reasonableness of conduct in tort law is stated as follows: `Where an act is one which a reasonable man would recognize as involving a risk of harm to another, the risk is unreasonable and the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.' [Citations.]" *1145 The Restatement Second of Torts adopted the same analysis. (Rest.2d Torts, § 291, pp. 54-56; accord, 6 Witkin, Summary of Cal. Law (9th ed. 1988) Torts, §§ 750-751, pp. 87-90.)

Simply stated, the foregoing statements of negligence law are permeated by the application of principles of reasonableness, and so is failure to warn in the context of a knowable risk. This court in *Brown* articulated a test permitting liability for failure to warn of reasonably knowable side effects. That is the functional equivalent of negligent conduct. If a drug manufacturer does not warn a tort plaintiff's physician of a reasonably knowable adverse risk of the drug, then in virtually every conceivable scenario, such failure would constitute negligence. Conversely, the failure to warn of a risk which is not reasonably knowable would not be negligence in any foreseeable context.

The only situation plaintiff posits for her contention there is a meaningful difference between negligence and failure to warn of a knowable risk theories involves an extraordinarily hypothetical possible industry-wide practice of failing to disclose an unreasonably dangerous side effect of a drug. She argues that drug manufacturers could adopt an industry-wide practice of not advising of particular side effects. This she reasons would defeat a negligence claim. No doubt, an industry-wide practice may be admissible as evidence of whether a corporation or decisionmaker of ordinary prudence would act negligently in not advising as to the dangerous side effects of a drug. (*Bullis* v. *Security Pac. Nat. Bank* (1978) 21 Cal.3d 801, 809 [148 Cal.Rptr. 22, 582 P.2d 109, 7 A.L.R.4th 642]; *Perumean* v. *Wills* (1937) 8 Cal.2d 578, 583 [67 P.2d 96].) Of course, such evidence would not be conclusive as a matter of law as to the standard of care in the industry. (*Bullis* v. *Security Pac. Nat. Bank, supra,* at p. 809; *Polk* v. *City of Los Angeles* (1945) 26 Cal.2d 519, 531-532 [159 P.2d 931].) However, if the drug were unreasonably dangerous, the conduct would in virtually every imaginable circumstance be a negligent act. In

fact, most jurors would be offended by such a practice. Moreover, if the danger were known, the manufacturer would be liable under the first prong of *Brown*; viz., failure to warn of a known risk.

Finally, creating a separate basis of liability for negligence and failing to warn of a reasonably scientifically knowable risk can only create confusion among jurors. Consider the confusion jurors experience when they read in the jury room BAJI Nos. 3.11, in which a test for negligence is provided, and 9.00.7, which delineates failure to warn principles. BAJI No. 3.11 states: "One test that is helpful in determining whether or not a person was negligent is to ask and answer the 1146 question whether or not, if a person of *1146 ordinary prudence had been in the same situation and possessed of the same knowledge, [he] [or] [she] would have foreseen or anticipated that someone might have been injured by or as a result of [his] [or] [her] action or inaction. If the answer to that question is `yes', and if the action or inaction reasonably could have been avoided, then not to avoid it would be negligence." Similar language appears in BAJI No. 9.00.7, which states as follows in part: "A product is defective if the use of the product in a manner that is reasonably foreseeable by the defendant involves a substantial danger that would not be readily recognized by the ordinary user of the product and the manufacturer knows or should have known of the danger, but fails to give adequate warning of such danger. [¶] [A manufacturer has a duty to provide an adequate warning to the user on how to use the product if a reasonably foreseeable use of the product involves a substantial danger of which the manufacturer either is aware or should be aware, and that would not be readily recognized by the ordinary user.]" Jurors will be confused when attempting to sort out negligence where a person would foresee or anticipate an injury from failure to warn of a danger the manufacturer should have known about. I have sat as a juror and seen how jurors can become overwhelmed and perplexed by comparatively simple legal concepts related in written instructions. Plaintiff's effort to distinguish negligence from failure to warn of a knowable risk liability is so ephemeral and likely to confuse and confound those in the fact-finding process, it should be abrogated particularly given the public policy concerns articulated by Justices Kennard and Baxter. (Conc. and dis. opn. of Kennard, J., *ante,* at pp. 1119, 1126, 1127-1129, 1131-1132; dis. opn. of Baxter, J., *post,* at pp. 1146-1147.)

III. CONCLUSION

I would affirm the opinion of the Court of Appeal insofar as it reverses the order of dismissal following the sustaining of the demurer without leave to amend.

BAXTER, J.

I dissent.

In this case we must determine whether, under California law, when a plaintiff seeks recovery against a manufacturer of a prescription drug on a "failure-to-warn" theory, the liability of the drug manufacturer may be determined under the same *strict liability* principles that generally apply to the manufacturers of all other products, or, instead, must be limited to general *negligence* principles.

We faced a somewhat comparable issue in *Brown* v. *Superior Court* (1988) 44 Cal.3d 1049 [245 Cal.Rptr. 412, 751 P.2d 470] (*Brown*). In *Brown,* a 1147 *1147 unanimous court concluded that, in light of the unique considerations related to the vital public interest in the development, availability, and reasonable pricing of prescription drugs, when a plaintiff seeks recovery against a prescription drug manufacturer for an injury allegedly caused by a "design defect" in the drug, the drug manufacturer's liability should *not* be based upon the same *strict liability* design-defect principles applicable to manufacturers of other products under California law, but instead should be limited to ordinary *negligence* principles. We concluded that a drug manufacturer may be held liable for an alleged design defect only when the plaintiff

establishes that the manufacturer was negligent in designing the drug. We additionally held in *Brown* that a manufacturer of a prescription drug may not be held strictly liable for failure to warn of risks posed by the drug *that were neither known nor scientifically knowable* at the time of the distribution of the drug. Our decision in *Brown,* however, did not explicitly address the question whether, with regard to risks *that were either known or scientifically knowable* at the time of distribution, a prescription drug manufacturer's liability for failure to warn could properly be premised upon strict liability, as well as upon negligence principles. That is the issue before us in this case.

The majority holds that a prescription drug manufacturer may be held strictly liable, on a failure-to-warn theory, for injuries arising from the ingestion or use of prescription drugs, *without consideration of the reasonableness of the manufacturer's conduct in furnishing the warnings that were given, or no warning*. I cannot subscribe to that result. For the reasons set forth below, I conclude that the same broad public policy considerations that led this court in *Brown, supra,* 44 Cal.3d 1049, to hold that the liability of manufacturers of prescription drugs for injuries caused by allegedly defectively designed drugs properly should be confined to negligence principles, also support a similar limitation — i.e., liability based solely upon negligence principles — when recovery is sought against a prescription drug manufacturer on a failure-to-warn theory. Indeed, that conclusion is even more compelled in the failure-to-warn context, where the necessity of furnishing warnings of the known or knowable dangerous propensities or other risks of harm posed by a prescription drug, and the content of such warnings where they are required, is heavily regulated and oftentimes dictated by federal law. Accordingly, I would reverse the judgment of the Court of Appeal, which reached a contrary conclusion.

I

Plaintiff's first amended complaint (complaint) alleges that defendant Upjohn Company (Upjohn) manufactured a prescription drug known as Halcion, to be used for the treatment of insomnia, 1148 among other conditions; *1148 that Halcion was unavoidably unsafe in that its use may cause emotional, physical, and psychic instability, distress, and injuries; and that these dangerous propensities were either known to Upjohn or reasonably scientifically knowable at the time that Halcion was distributed and ingested by plaintiff. The complaint further alleges that plaintiff obtained a prescription for Halcion from a physician and ingested the drug during the time period from 1987 through November 1992. As a proximate result, plaintiff sustained serious injuries to her health, strength, and nervous system, and suffered extreme mental distress. The complaint purports to state causes of action in (1) strict liability for defective preparation and for failure to warn of the known or scientifically knowable dangerous propensities of Halcion, (2) negligence, (3) breach of express and implied warranties, and (4) fraud.[1]

[1] The complaint also states causes of action for medical malpractice against defendants Valentino Andres, Jr., M.D., and Valentino Andres, Jr., M.D., Inc., a professional corporation.

Upjohn demurred to the causes of action in strict liability and breach of express and implied warranties (among other causes of action), maintaining that, under *Brown, supra,* 44 Cal.3d 1049, a drug manufacturer is exempt from strict liability and breach of warranty liability based upon a failure to warn and may be held liable for failure to warn solely upon a negligence theory. The trial court sustained the demurrer without leave to amend both as to the cause of action in strict liability, citing *Brown, supra,* 44 Cal.3d 1049, and *Artiglio* v. *Superior Court* (1994) 22 Cal.App.4th 1388 [27 Cal.Rptr.2d 589] (containing dictum construing *Brown* as limiting liability for failure to warn to a negligence theory),

and as to the cause of action for breach of express and implied warranties, citing *Brown*. After her motion for reconsideration was denied, plaintiff filed a petition for writ of mandate or other appropriate relief in the Court of Appeal, seeking to vacate the trial court's order.

The Court of Appeal issued an alternative writ and, after full briefing and argument, issued a peremptory writ of mandate, directing the trial court to vacate its order sustaining Upjohn's demurrer to plaintiff's causes of action for strict liability and breach of warranty, and to enter a new order overruling the demurrer to those causes of action. In its opinion, the Court of Appeal concluded that any ambiguity in the *Brown* decision as to whether a drug manufacturer may be held liable on a theory of strict liability based upon an asserted failure to warn of known or knowable risks of harm of a drug, was resolved in plaintiff's favor in our post- *Brown* decision in *Anderson* v. *Owens-Corning Fiberglas Corp*. (1993) 53 Cal.3d 987 [281 Cal.Rptr. 528, 810 P.2d 549] (*Anderson*). With respect to the cause of action for breach of warranty, the Court of Appeal concluded that such a claim against such a prescription drug manufacturer is not precluded under *Brown* to the extent *1149 the claim is based upon a failure to warn for which the manufacturer may be held strictly liable.

We granted review to clarify the scope and significance of the principles and holdings in *Brown, supra,* 44 Cal.3d 1049, and *Anderson, supra,* 53 Cal.3d 987, as they pertain to the issue of whether a prescription drug manufacturer may be held liable on theories of strict liability or breach of warranty for failure to warn of the dangerous propensities or other risks of harm posed by a prescription drug.[2]

[2] The following organizations have filed briefs amicus curiae in support of real party in interest Upjohn: Association For California Tort Reform; California Chamber of Commerce and California Manufacturers Association; California Medical Association; Product Liability Advisory Council, Inc.; and Pharmaceutical Research and Manufacturers of America.

II

The doctrine of strict liability imposes legal responsibility, without proof of negligence, upon the manufacturer of a product that is placed on the market and proves to have a defect that causes injury. (*Greenman* v. *Yuba Power Products, Inc*. (1963) 59 Cal.2d 57, 62 [27 Cal.Rptr. 697, 377 P.2d 897, 13 A.L.R.3d 1049].) Strict liability differs from negligence in that it focuses not upon the conduct of the manufacturer but upon the product itself; the plaintiff need not prove that the manufacturer acted unreasonably or negligently in order to prevail, but only that the product was defective. (*Barker* v. *Lull Engineering Co*. (1978) 20 Cal.3d 413, 418, 432 [143 Cal.Rptr. 225, 573 P.2d 443, 96 A.L.R.3d 1].) The policy considerations underlying the strict liability doctrine are premised upon the assumptions that the manufacturer can anticipate or guard against the recurrence of hazards and that the cost of injury may be overwhelming to the person injured, whereas the manufacturer can insure against the risk and distribute the cost among the consuming public. (*Brown, supra,* 44 Cal.3d at p. 1056.) Additionally, the doctrine relieves an injured plaintiff of many of the "onerous evidentiary burdens inherent in a negligence cause of action." (*Barker* v. *Lull Engineering Co., supra,* 20 Cal.3d at p. 431.)

As our past cases explain, strict liability may be invoked for three types of injury-producing defects: (1) a manufacturing defect, where the product deviates from the manufacturer's intended result; (2) a design defect, where the product either fails to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner, or when the risk of danger inherent in the design outweighs the benefits of the challenged design; and (3) a "warning" defect, where the product lacks adequate instructions or

warnings as to risks of harm. (*Barker* v. *Lull* 1150 *Engineering Co.,* *1150 *supra,* 20 Cal.3d at pp. 428-430.) In the latter category, the injured plaintiff alleges, not that the manufacture or design of the product was defective, but that the manufacturer failed to warn of potential dangers in the use of its product. If the injury could have been prevented with appropriate warnings, the absence of such warnings is deemed to render the product "defective" in the eyes of the law. (*Midgley* v. *S.S. Kresge Co*. (1976) 55 Cal.App.3d 67, 71-72 [127 Cal.Rptr. 217], and cases cited.)

As regards the third category of defect, i.e., a warning defect, this court's recent decision in *Anderson, supra,* 53 Cal.3d 987, decided five years after our decision in *Brown, supra,* 44 Cal.3d 1049, concluded that under *generally applicable* principles of strict liability for failure to warn, a manufacturer of any product may be held strictly liable for injuries caused by failure to provide adequate warnings of a product's dangerous propensities or risks only if such propensities *were known or scientifically knowable at the time of distribution*. (*Anderson, supra,* 53 Cal.3d at pp. 1003-1004.)

Long before our decision in *Brown, supra,* 44 Cal.3d 1049, the drafters of the Restatement Second of Torts recognized that because of fundamental differences between prescription drugs and other products, it would be contrary to the public interest to subject prescription drug manufacturers to generally applicable strict liability principles. Imposition of such far-reaching liability would risk stifling needed medical research and the testing and marketing of essential, highly beneficial, but inherently dangerous drugs. Comment k to section 402A of the Restatement[3] provides that the sellers of both established and experimental drugs are exempt from strict liability if the drugs are prepared properly and accompanied by appropriate warnings of known risks. (44 Cal.3d at p. 354.) Comment k states in full: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it *unreasonably* dangerous. The same is true of 1151 many other drugs, vaccines, *1151 and the like, many of which for this very reason cannot be legally sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." (*Id*. at pp. 353-354, italics in original.)

[3] Section 402A of the Restatement Second of Torts, pages 347-348, provides in part: " (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if [¶] (a) the seller is engaged in the business of selling such a product, and [¶] (b) it is expected to

> and does reach the user or consumer without substantial change in the condition in which it is sold."

As we explained in *Brown, supra,* 44 Cal.3d at page 1059, comment k to section 402A of the Restatement Second of Torts has been adopted in the overwhelming majority of jurisdictions that have considered the issue of the standard for imposition of liability upon prescription drug manufacturers for injuries resulting from dangerous propensities and other risks of harm emanating from prescription drug products. (See, e.g., *DeLuryea* v. *Winthrop Laboratories, etc*. (8th Cir. 1983) 697 F.2d 222, 229; *Lindsay* v. *Ortho Pharmaceutical Corp*. (2d Cir. 1980) 637 F.2d 87, 91; *Werner* v. *Upjohn Co., Inc*. (4th Cir. 1980) 628 F.2d 848, 858; *Salmon* v. *Parke, Davis and Co*. (4th Cir. 1975) 520 F.2d 1359, 1362; *Basko* v. *Sterling Drug, Inc*. (9th Cir. 1969) 416 F.2d 417, 426; *Stone* v. *Smith, Kline French Lab*. (Ala. 1984) 447 So.2d 1301, 1303-1304; *Johnson* v. *American Cyanamid Co*. (1986) 239 Kan. 279 [718 P.2d 1318, 1323, 66 A.L.R.4th 55]; *Seley* v. *G.D. Searle 7 Co*. (1981) 67 Ohio St.2d 192 [21 Ohio Ops.3d 121, 423 N.E.2d 831].) These courts as well as legal commentators have construed comment k as providing, in general, that a manufacturer of an unavoidably unsafe, but properly prepared, prescription drug shall *not* be held strictly liable to a consumer who has suffered injury as a result of ingesting that drug.

There is a general consensus that the standard for imposition of liability under comment k to section 402A of the Restatement Second of Torts is that of negligence, focusing upon the conduct of the manufacturer and whether the manufacturer exercised reasonable care in warning of potential dangers of which it knew or in the exercise of reasonable care should have known. (See *DeLuryea* v. *Winthrop Laboratories, etc., supra,* 697 F.2d at pp. 228-229; *Lindsay* v. *Ortho Pharmaceutical Corp., supra,* 637 F.2d at p. 91; *Salmon* v. *Parke, Davis and Co., supra,* 520 F.2d at p. 1362; *Basko* v. *Sterling Drug, Inc., supra,* 416 F.2d at pp. 425-426; Prosser Keeton on Torts (5th ed. 1984) § 99, p. 697). Under a negligence standard, liability is imposed only where the evidence would support a finding that a reasonable
1152 person in *1152 the position of the manufacturer, held to the standard of an expert in the field, would have foreseen a risk of harm posed by the drug and would have provided a reasonable warning. (See McClellan, *Strict Liability for Drug Induced Injuries: An Excursion Through the Maze of Products Liability, Negligence and Absolute Liability* (1978) 25 Wayne L. Rev. 1, 2.) Dean Prosser earlier summarized the liability of prescription drug manufacturers under this standard as follows: "Thus far the courts have tended to hold the manufacturer to a high standard of care in preparing and testing drugs of unknown potentiality and in giving warning; but in the absence of evidence that this standard has not been met, they have refused to hold the maker liable for unforeseeable harm." (Prosser on Torts (4th ed. 1971) § 99, p. 661, fns. omitted.)

In *Brown,* this court held that prescription drug manufacturers are not subject to strict liability for a " *design defect*" under the standard applicable, under California law, to manufacturers of other products under our decision in *Barker* v. *Lull Engineering Co., supra,* 20 Cal.3d 413. (*Brown, supra,* 44 Cal. 3d at pp. 1061-1065.) Adopting the standard under comment k to section 402A of the Restatement Second of Torts, which we characterized as being based upon negligence principles,[4] we held that a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was prepared properly and accompanied by warnings of those dangerous propensities that either were known or reasonably scientifically knowable at the time of distribution. (*Id*. at p. 1069.)

> [4] We observed in *Brown:* "Comment k has been analyzed and criticized by numerous commentators. While there is some disagreement as to its scope and meaning, there is a general consensus that, although

> it purports to explain the strict liability doctrine, *in fact the principle it states is based on negligence*. (E.g., Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K* (1985) 42 Wn. Lee L. Rev. 1139, 1141; McClellan, *Drug Induced Injury* (1978) 25 Wayne L.Rev. 1, 2; Kidwell, *The Duty to Warn: A Description of the Model of Decision* (1975) 53 Tex.L.Rev. 1375, 1377-1378; Merrill, *Compensation for Prescription Drug Injuries* (1973) 59 Va.L.Rev. 1, 50.)" (*Brown, supra,* 44 Cal.3d at p. 1059, italics added.)

In reaching that conclusion, we reasoned that in light of fundamental distinctions between prescription drugs and other products, and because prescription drugs may cause untoward side effects even though properly and carefully prepared, the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use. (44 Cal.3d at p. 1063.) We determined that the imposition of strict liability for design defects would have the undesirable consequence of inhibiting the development and marketing of essential and highly beneficial medications at affordable prices. We explained: "Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge 1153 advanced to the point at which *1153 additional dangerous side effects would be revealed. But in most cases such a delay in marketing new drugs — added to the delay required to obtain approval for release of the product from the Food and Drug Administration — would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering. [¶] If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability — assuming insurance would be available — and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most." (*Brown, supra,* 44 Cal. 3d at p. 1063.)

We also noted in *Brown* that the consumers of prescription drugs are afforded greater protection against defects than the consumers of other products, because the drug industry is closely regulated by the Food and Drug Administration, which actively controls the testing, manufacture, and marketing of drugs. (44 Cal. 3d at p. 1069, fn. 12.)

We concluded in *Brown* that, for these reasons, the negligence standard embodied in comment k to section 402A of the Restatement Second of Torts, rather than principles of strict liability, must govern a prescription drug manufacturer's liability for injuries caused by the defective design of a drug. (44 Cal.3d at p. 1065.) We held further that the plaintiff's claims for breach of express or implied warranty against a prescription drug manufacturer were "inconsistent with our determination on the issue of strict liability for design defects," and therefore upheld the trial court's pretrial rulings disallowing the claims for breach of warranty. (*Id*. at p. 1072.)

The procedural posture of *Brown,* as that case reached this court, required us to address, in addition to the question of strict liability and breach of warranty for *design defect,* the plaintiff's further contention that a drug manufacturer could be held strictly liable for failure to warn of *unknowable* risks of harm. The trial court had made pretrial rulings that the defendants could be held strictly liable for their failure to warn of the drug's known or knowable side effects, which ruling was not challenged by defendants on

appeal. Instead, the plaintiff argued that the trial court had not gone far enough and sought a ruling that a drug manufacturer could be held strictly liable for failure to warn of risks inherent in a drug even though the manufacturer neither knew, nor could have known by the application of scientific knowledge available at the time of distribution, 1154 that the drug could *1154 produce the undesirable side effects. While recognizing a split of authority on the issue, we observed in *Brown* that the majority view in products liability cases in general is that a manufacturer will be liable only for failure to warn of those risks of which the manufacturer had actual or constructive knowledge as of the time the product was distributed. (44 Cal.3d at pp. 1065-1066.) We therefore concluded in *Brown,* in accordance with the majority view in products liability cases generally, and consistent with the rationale of comment k to section 402A of the Restatement Second of Torts, that a prescription drug manufacturer may not be held strictly liable for failure to warn of unknown or unknowable side effects. (44 Cal. 3d at p. 1066.)

Because of the nature of the pretrial rulings and the issues raised on appeal in *Brown, supra,* 44 Cal.3d 1049, we were *not* in that case directly presented with the precise issue before us in the present case — whether a drug manufacturer should be subject to the same strict liability *failure-to-warn* principles that are generally applicable to manufacturers of other products. Our opinion in *Brown* did suggest, however, that liability for failure to warn *in the prescription drug context* was governed by comment k to section 402A of the Restatement Second of Torts, and, in a footnote, we acknowledged that failure-to-warn liability under comment k was analytically distinct from general principles of strict liability.[5]

[5] Footnote 4 of our opinion in *Brown* explains, in relevant part: "The test stated in comment k is to be distinguished from strict liability for failure to warn. Although both concepts identify failure to warn as the basis of liability, comment k imposes liability only if the manufacturer knew or should have known of the defect at the time the product was sold or distributed. Under strict liability, the reason why the warning was not issued is irrelevant, and the manufacturer is liable even if it neither knew nor could have known of the defect about which the warning was required." (*Brown, supra,* 44 Cal.3d at p. 1059, fn. 4.)

As explained more fully below, this court's subsequent decision in *Anderson, supra,* 53 Cal.3d 987, made it clear — contrary to the possible implication contained in footnote 4 of the *Brown* opinion — that even under strict liability principles, strict liability for failure to warn can be based only upon risks that were either known or scientifically knowable at the time the product was distributed. Nonetheless, footnote 4 of our *Brown* opinion reflects that this court understood the rationale of comment k as essentially embodying a negligence failure-to-warn standard. When read together with the subsequent discussion in our opinion in *Brown* endorsing the comment k test for manufacturers of prescription drugs, footnote 4 strongly suggests we were of the view in *Brown* that a prescription drug manufacturer's liability for failure to warn would be governed by ordinary negligence principles.

Five years after our decision in *Brown, supra,* 44 Cal.3d 1049, this court was presented with the question whether, under general principles of strict liability applicable to all products, a manufacturer could be held strictly liable for a "warning" defect when the risk of harm as to which no warning had been given *was neither known nor scientifically knowable at the time the product was distributed*. In *Anderson, supra,* 53 Cal.3d 987, a case that involved asbestos-related injury, *not* prescription drugs, we clarified that in products liability cases

generally, a manufacturer may not be held strictly liable for failure to warn of unknown or unknowable risks of harm. *1155

The precise issue presented in *Anderson* was whether a defendant in a products liability action, based upon an alleged failure to warn of a risk of harm, may present evidence of the "state of the art" — i.e., evidence that the particular risk was neither known nor knowable by the application of scientific knowledge available at the time of manufacture or distribution. (53 Cal.3d at p. 990.) We determined in *Anderson* that such state-of-the-art evidence was properly admissible in a products liability action. In reaching this conclusion, we recognized the body of decisional law establishing a theory of strict liability based upon a manufacturer's failure to warn of a product's known or scientifically knowable dangerous propensities, and reviewed the discussion of authorities in our opinion in *Brown* on the issue of whether strict liability for failure to warn *presupposes knowledge* of the risk on the part of the manufacturer. We concluded in *Anderson* that "California is well settled into the majority view that knowledge, actual or constructive, is a requisite for strict liability for failure to warn." (53 Cal.3d at p. 1000.)

Contrary to the contention of plaintiff and the conclusion of the majority in the present case, I do not believe this court's opinion in *Anderson* properly may be understood as holding that the failure-to-warn strict-liability standard generally applicable to manufacturers of other products necessarily applies to manufacturers of prescription drugs.

First, because *Anderson* was not a prescription drug case, this court had no occasion therein to directly consider or address the broader policy question of whether failure-to-warn strict liability should apply to prescription drug manufacturers. We did, however, place reliance on our earlier opinion in *Brown, supra,* 44 Cal.3d 1049, a prescription drug case, in reaffirming the settled majority view that "knowledge, actual or constructive" is a requisite component of strict liability for failure to warn. (*Anderson, supra,* 53 Cal.3d at p. 1000.)[6] But we simply did not in *Anderson* further consider, much less reject, application of *Brown*'s important public policy rationale — which led *1156 us in that case to exempt prescription drug manufacturers from strict liability for design defects in furtherance of the "broader public interest" in the development and marketing of beneficial new drugs — to the specific question of whether prescription drug manufacturers should likewise be exempt from strict liability in failure-to-warn actions.

6 Justice Mosk, who authored the opinion for the court in *Brown, supra,* 44 Cal.3d 1049, wrote separately in *Anderson* and criticized the majority's reliance on *Brown:* "The [*Anderson*] majority rely extensively on [*Brown*]. They obviously fail to comprehend that *Brown* was based on a narrow public policy exception to strict products liability for prescription drugs, and for such drugs alone. We emphatically declared in *Brown* (at p. 1063) that `there is an important distinction between prescription drugs and other products,' and we elaborated on the reason for the distinction: `Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering.' (*Ibid.*) We added that `the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability from injuries resulting from their use.' (*Ibid.*) The [*Anderson*] majority stretch the holding and the analysis in *Brown* beyond all recognition when they rely on that case in [asbestos injury] litigation involving products other than prescription drugs." (*Anderson, supra,* 53 Cal.3d 987, 1008 (conc. and dis. opn. of Mosk, J.).)

Second, as already explained, in this court's unanimous decision in *Brown* we plainly suggested that a prescription drug manufacturer's liability, under comment k to section 402A of the Restatement Second of Torts for failure to warn, was governed by a *negligence* standard (44 Cal.3d at p. 1059, fn. 4), whereas in *Anderson* we explicitly recognized a marked distinction between failure to warn under a strict liability standard and failure to warn under a negligence standard. Our observations in *Anderson* regarding the distinction between negligence and strict liability in failure-to-warn actions bears closer scrutiny here.

The majority herein correctly observe that "in the failure-to-warn context, strict liability is to some extent a hybrid of traditional strict liability and negligence doctrine." (Maj. opn., *ante,* at p. 1112.) In *Anderson* we explained that "the claim that a particular component `rings of' or `sounds in' negligence has not precluded its acceptance in the context of strict liability." (53 Cal.3d at p. 1001.)

In his separate concurring and dissenting opinion in *Anderson,* Justice Mosk elaborated on the point: "[T]he focus [between strict products liability and negligence] has become blurred through the years. . . . [T]his court has incorporated a number of principles of the law of negligence into strict liability doctrine. (See, e.g., *Luque* v. *McLean* (1972) 8 Cal.3d 136, 145 [104 Cal.Rptr. 443, 501 P.2d 1163] [assumption of risk defense]; *Daly* v. *General Motors Corp*. [(1978)] 20 Cal.3d 725, 736-737 [144 Cal.Rptr. 380, 575 P.2d 1162] [comparative negligence]; *Barker* v. *Lull Engineering Co., supra,* 20 Cal.3d 413, 432 [risk-benefit test]; *Brown* v. *Superior Court* (1988) 44 Cal.3d 1049, 1066 [245 Cal.Rptr. 412, 751 P.2d 470] [as a matter of policy, strict liability standards not applicable to prescription drug manufacturers].)" (*Anderson, supra,* 53 Cal.3d at p. 1006 (conc. and dis. opn. of Mosk, J.).)

Similarly, "[t]he courts of some of our sister states . . . have permitted the infusion of negligence concepts into failure-to-warn strict liability actions. (See, e.g., *Gonzales* v. *Volvo of America Corp*. (7th Cir. 1985) 752 F.2d 295, 300 [language and concepts of reasonableness in strict liability failure-to-warn cases under Indiana law same as those applied in negligence cases]; *Borel* v. *Fibreboard Paper Products Corporation* (5th Cir. 1157 1973) *1157 493 F.2d 1076, 1088 [same under Texas law]; *Bernier* v. *Raymark Industries, Inc*. (Me. 1986) 516 A.2d 534, 538 [reasonableness of defendant's conduct is a factor]; *Feldman* v. *Lederle Laboratories* (1984) 97 N.J. 429 [479 A.2d 374, 385] [same]; *Bilotta* v. *Kelley Co., Inc*. (Minn. 1984) 346 N.W.2d 616, 622 [strict liability failure-to-warn claims based on negligence concepts]; and see generally, Henderson Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn* (1990) 65 N.Y.U.L. Rev. 265, 271-273; Prosser Keeton, The Law of Torts (1988 supp.) § 99, p. 95, fn. 21; Bromberg, *The Mischief of the Strict Liability Label in the Law of Warnings* (1987) 17 Seton Hall L. Rev. 526, 534-535.)" (*Anderson, supra,* 53 Cal.3d at p. 1007 (conc. and dis. opn. of Mosk, J.).)

In light of this state of the law, the question might reasonably be posed — has the melding of negligence concepts into strict liability doctrine in failure-to-warn cases obliterated all significant distinctions between the two theories of liability? If the answer is yes, then perhaps, as one justice of this court has suggested, "[w]e should consider the possibility of holding that failure-to-warn actions lie solely on a negligence theory. `[A]lthough mixing negligence and strict liability concepts is often a game of semantics, the game has more than semantic impact — it breeds confusion and inevitably, bad law.' (Henderson Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, supra,* 65 N

YU.L. Rev. at p. 278.)" (*Anderson, supra,* 53 Cal.3d at p. 1008 (conc. and dis. opn. of Mosk, J.).)

To my mind, however, our opinion in *Anderson* answered the question — negligent failure to warn and strict-liability failure to warn remain analytically distinct theories of liability. Although there can be no doubt that this court, the courts of appeal, courts of our sister states, and many noted legal commentators and authorities, have long acknowledged the infusion of concepts of negligence into strict liability doctrine generally, and strict liability failure-to-warn actions specifically, in *Anderson* we nonetheless determined that "despite its roots in negligence, failure to warn in strict liability differs markedly from failure to warn in the negligence context." (*Anderson, supra,* 53 Cal.3d at p. 1002.) We went on to explain: "Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Thus, in *1158 strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial." (*Id*. at pp. 1002-1003, fn. omitted.)[7]

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> [7] In contrasting strict liability failure to warn with negligent failure to warn, we observed in *Anderson* that "a reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacturer's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles. In contrast, under strict liability principles the manufacturer has no such leeway; the manufacturer is liable if it failed to give warning of dangers that were known to the scientific community at the time it manufactured or distributed the product." (53 Cal.3d at p. 1003.)

In sum, our decision in *Anderson, supra,* 53 Cal.3d 987 distinguished failure-to-warn actions sounding in negligence from failure-to-warn actions premised on strict liability, and found that although there is significant overlap between the elements of those two theories of liability, there remain marked differences as well. *Anderson* further holds that, *as a general matter,* although a manufacturer can be found strictly liable for failing to warn of the known or scientifically knowable risks of harm associated with its products, the *reasonableness* of the manufacturer's conduct surrounding the giving of a particular warning, or no warning at all, is "immaterial" to a failure-to-warn action premised on strict liability. (*Anderson, supra,* 53 Cal.3d at pp. 1002-1003.) Notably, what our opinion in *Anderson* did *not* do is address or resolve the broader public policy question of whether *a prescription drug manufacturer* should be exempt from *strict liability* for failing to warn of the dangerous propensities or harmful risks of its products. It is to that question that I turn next.

III

For the reasons hereafter explained, I conclude that the same important public policy considerations relating to the development, marketing, and availability of prescription drugs that led this court in *Brown* to conclude that principles of strict liability (and breach of warranty liability) generally applicable to "design defects" should not be extended to manufacturers of prescription drugs, should apply as well to failure-to-warn defects. I would therefore hold in

this case that it is solely under negligence principles that a prescription drug manufacturer may be held liable for failure to warn.

First, as recognized by several legal commentators, a product's "warning" may be characterized as part of its overall design, and in many cases the question of the adequacy of warnings is a subset of the question of the acceptability of the basic design. (See, e.g., Twerski, *The Use and Abuse of Product Warnings in Products Liability — Design Defect Litigation Comes of* *1159 *Age* (1976) 61 Cornell L.Rev. 495, 500-501, 510.)[8] Many of the considerations involved in the determination of a design defect are equally applicable to a "failure-to-warn" defect, including a risk-utility balancing and, specifically, the balancing of the benefits of possible warnings against design alternatives. For example, in the prescription drug context, if the probability of harmful side effects from a beneficial new prescription drug is statistically remote, the question may arise whether to warn against them at all. Or the inquiry may instead focus on consideration of whether additional research could lead to a safer reformulation of the drug, thereby obviating the need for any warnings. Thus, "the questions of warning and design are often inextricably woven together." (*Id*. at p. 524.) It follows, then, that to the extent important public policy considerations led this court in *Brown* to exempt prescription drug manufacturers from strict liability for *design defects,* those same considerations should be applied to exempt prescription drug manufacturers from strict liability for *failure to warn* of the known or scientifically knowable risks of harm or harmful side effects associated with its products.

8 As noted above (*ante,* at p. 1150), courts that have addressed the issue of products liability "warning" defects have reasoned that if injury caused by a product could have been prevented with appropriate warnings, the absence of such warnings is itself deemed to render the product "defective" in the eyes of the law. (*Midgley* v. *S.S. Kresge Co., supra,* 55 Cal.App.3d at pp. 71-72, and cases cited.)

Second, as noted above, long before our decision in *Brown* v. *Superior Court, supra,* 44 Cal.3d 1049, the drafters of the Restatement recognized that because of fundamental differences between prescription drugs and other products, it would be contrary to the public interest to subject prescription drug manufacturers to generally applicable strict liability principles because imposition of such far-reaching liability would risk stifling needed medical research and the testing and marketing of essential, highly beneficial, but inherently dangerous drugs. I have explained how this court in *Brown* concluded that liability for failure to warn *in the prescription drug context* should be governed by the standard of liability set forth in comment k to section 402A of the Restatement Second of Torts, and how, in a footnote to our opinion in that case, we further reasoned that failure-to-warn liability under comment k was analytically distinct from general principles of strict liability, and that comment k in actuality set forth a standard that incorporated fundamental concepts of negligence. (*Brown, supra,* 44 Cal.3d at p. 1059, fn. 4.)

I note that related provisions in the American Law Institute's tentative draft of the Restatement Third of Torts pertaining to products liability buttress my conclusion that the drafters of the Restatement have long viewed, and continue to view, failure-to-warn liability in prescription drug *1160 cases as requiring application of a *negligence* standard of liability. Section 8 of that tentative draft, entitled "Liability of Commercial Seller or Distributor for Harm Caused by Prescription Drugs and Medical Devices," provides in pertinent part: "(d) A prescription drug . . . is not reasonably safe because of inadequate instructions or warnings when [¶] (1) *reasonable* instructions or warnings regarding *foreseeable* risks of harm posed by the drug . . . are not provided to prescribing and other health care providers who

are in a position to reduce the risks of harm in accordance with the instructions or warnings. . . ." (Rest.3d Torts: Products Liability (Tent. Draft No. 2, Mar. 13, 1995) § 8, p. 210, italics added.) Clearly, by incorporating concepts of "reasonableness" and "foreseeability" into the new standard, the drafters of the new Restatement intend to impose a standard of care *sounding in negligence* in failure-to-warn actions involving prescription drugs. (See also *Ellis* v. *Chicago Bridge Iron Co*. (1988) 376 Pa. Super. 200 [545 A.2d 906, 912-913] ["The liability arising from inadequate warnings is not `strict' in the same sense as liability arising from a defect due to fault in manufacture, since a determination of whether an object is unreasonably dangerous without adequate warnings, and thus defective, necessarily involves negligence principles such as reasonableness or foreseeability." (Fn. omitted.)].)

Third, in the warning context, as in the design-defect context, the existence and role of the federal Food and Drug Administration (FDA) provides a justification for distinguishing prescription drugs from other products, because one of the FDA's primary functions is to evaluate the necessity and adequacy of warnings provided by prescription drug manufacturers. In *Anderson,* as we have seen, this court suggested that generally a product manufacturer might escape liability under negligence principles "if the manufacturer's own testing showed a result contrary to that of others in the scientific community." (53 Cal. 3d at p. 1003.) In the prescription drug industry, however, a manufacturer is not left to its own resources to decide whether the risk of harm is such as to require a warning. Rather, the FDA plays a significant role in determining whether a warning must be provided, and, if so, the specific content of the warning.[9]

[9] The FDA's approval of a particular warning is, of course, not determinative of liability. (See *Abbott by Abbott* v. *American Cyanimid Co*. (4th Cir. 1988) 844 F.2d 1108, 1112, 1115 [98 A.L.R.Fed. 107]; *Brochu* v. *Ortho Pharmaceutical Corp*. (1st Cir. 1981) 642 F.2d 652, 658; *Feldman* v. *Lederle Laboratories* (1991) 125 N.J. 117 [592 A.2d 1176, 1189].) "[M]ere compliance with regulations or directives as to warnings, such as those issued by the United States Food and Drug Administration . . ., may not be sufficient to immunize the manufacturer or supplier of the drug from liability. The warnings required by such agencies may be only minimal in nature and when the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled." (*Stevens* v. *Parke, Davis Co*. (1973) 9 Cal.3d 51, 65 [107 Cal.Rptr. 45, 507 P.2d 653, 94 A.L.R.3d 1059].) A jury may still find a drug manufacturer negligent, for example, if it failed to comply with FDA regulations or with professional or scientific standards in conducting the tests that it reported to the FDA.

It seems clear that the FDA regulations applicable to prescription drugs and their accompanying warnings, and various factors such as the presence
1161 *1161 or absence of a prior FDA approval requirement, whether FDA approval has been obtained for a particular warning, or whether authorization has been obtained to forego the furnishing of a warning altogether — are all highly relevant in determining liability in actions for failure to warn brought against prescription drug manufacturers under state tort laws, and of necessity will require inquiry into the *reasonableness* of the manufacturer's individualized conduct in its efforts to comply with the FDA warning requirements, and the *foreseeability* of the need for such warnings in the first instance.[10] Concepts such as "reasonableness" and "foreseeability" are fundamentally rooted in negligence doctrine. To fail to apply them, and instead hold prescription drug manufacturers *strictly liable* for failing to warn of the risks of

harm associated with their products, would effectively preclude consideration of evidence highly relevant to the question of fault in the failure-to-warn context.

10 There can be no dispute that the labeling of prescription drugs, and the necessity of accompanying warnings, is a highly regulated matter. (See, e.g., 21 U.S.C. § 301 et seq. [labeling regulations promulgated under the federal Food, Drug, and Cosmetic Act]; *id.,* § 321(m) [broadly defining "labeling"]; 21 C.F.R. § 201.57 (1996) [listing regulations specifically governing labeling of prescription drugs]; *id.,* § 1.21(c) (1996) [label warnings regarding contraindications, precautions, adverse reactions, and other possible risks of harm may not include statements of differences of opinion within the medical community]; *id.,* § 201.57(e) (1996) [warnings must include " *serious* adverse reactions and potential safety hazards" and must be revised "as soon as there is *reasonable evidence* of an association of a serious hazard with a drug" (italics added)]; *id.,* § 201.57(f)(6) (1996) [specific warning language mandated where risks related to pregnancy are involved].)

Moreover, it has generally been recognized that a prescription drug manufacturer should not be held liable where there is an *actual conflict* between federal regulations and state tort law requirements, i.e., where it is impossible to comply with both. (See, e.g., *Feldman* v. *Lederle Laboratories, supra,* 592 A.2d 1176, 1185.) One line of authority holds further that where an FDA-approved or -mandated warning has issued, and the manufacturer could not thereafter change the language of the warning without FDA approval, the manufacturer could not be held liable for failing to furnish additional warnings. (See *Hurley* v. *LeDerle Lab. Div. of American Cyanamid* (5th Cir. 1988) 863 F.2d 1173, 1179; *Spychala* v. *G.D. Searle Co*. (D.N.J. 1988) 705 F. Supp. 1024, 1033; but see *Feldman* v. *Lederle Laboratories, supra,* 592 A.2d at p. 1192 [use of an FDA-approved warning does not insulate prescription drug manufacturer from liability for failure to warn of known or knowable risks of harm, as the federal labeling regulations set forth only minimum requirements, and prior FDA approval is generally not required before warning of known or knowable risks]; *Brochu* v. *Ortho Pharmaceutical Corp., supra,* 642 F.2d 652, 657-658 [same].)

In short, the existence of the FDA regulatory process provides a basis for distinguishing drug manufacturers from the manufacturers of other products that may be placed on the market without such rigorous scrutiny and evaluation of the necessity of accompanying warnings and their
1162 contents by a federal regulatory agency. *1162

Fourth, I believe that subjecting prescription drug manufacturers to a strict liability standard for failure to warn would create a risk of inhibiting or delaying the development and marketing of new drugs that is comparable to the risk that the court in *Brown* determined was contrary to the public interest. Under a strict liability standard, because of the inherently dangerous nature of prescription drugs a manufacturer could risk astronomical liability for failure to warn of risks of harm even though it acted in accordance with the high standard of care of a reasonably prudent manufacturer. Thus, even when a drug manufacturer has acted reasonably in refraining from expending additional time and money that would have delayed the availability and increased the price of a new drug, under strict liability principles the manufacturer could be held liable in the event a jury determined there were scientifically knowable risks of harm as to which a warning could have been given. If such a legal standard were applicable to manufacturers of prescription drugs, a manufacturer might hesitate to develop or market new drugs (especially less profitable products) because of such unknown and unassessable liability. In contrast, if liability is

limited to those situations in which the manufacturer fails to act reasonably in providing warnings, the manufacturer that, in developing and marketing a drug, does its best to ensure that its employees adhere to all of the high professional and regulatory standards applicable to experts in the field, may have confidence that the future liability it incurs as a result of marketing the drug will remain within reasonable, insurable limits.

Admittedly, under a negligence standard, some consumers of prescription drugs may be denied compensation for injuries resulting from the absence of warnings of risks of harm that were scientifically knowable but reasonably not known by the manufacturer at the time a prescription drug was sold. Nevertheless, I conclude, as did this court in *Brown,* that on balance the public is better served by increasing the likely availability of affordable, highly beneficial prescription drugs than by extending a strict liability cause of action for monetary compensation to those persons who are injured despite the reasonable actions of prescription drug manufacturers.

IV

For all of the foregoing reasons, I conclude that a prescription drug manufacturer's liability for injuries arising from failure to warn of the risks of harm posed by a drug should be restricted to a 1163 negligence standard, and *1163 that such a manufacturer should not be liable for failure to warn under theories of strict liability or breach of implied warranty.[11]

11 *Brown, supra,* 44 Cal.3d at pages 1071-1072, holds that a plaintiff cannot pursue a *breach-of-warranty* design-defect claim against a prescription drug manufacturer for the same reasons he or she cannot pursue a *strict liability* design-defect claim against a prescription drug manufacturer. This is so because the "consumer expectation test," which is at the heart of a strict products liability claim (see *Barker* v. *Lull Engineering Co., supra,* 20 Cal.3d at pp. 429-430), is conceptually analogous to a claim of implied warranty of fitness, and the application of such theory of liability to design-defect actions in the prescription drug context was *rejected* in *Brown*. (44 Cal.3d at pp. 1061-1062, 1071-1072, and fn. 14.)

The majority seek to disavow *Brown*'s holding in this regard by suggesting *Brown* merely rejected the suitability of warranty claims arising from design defects that are "neither known nor knowable at the time the drug is distributed." (Maj. opn., *ante,* at p. 1118.) This is a specious distinction, particularly when one considers the statement in the footnote appended to the paragraph the majority is quoting from *Brown,* which the majority ignores, but which explains: "our holding regarding plaintiff's breach of warranty claims is founded on the inconsistency between such claims and our conclusion that prescription drugs are not subject to strict liability for design defects. . . ." (*Brown, supra,* 44 Cal.3d at p. 1072, fn. 14.) The majority's faulty reasoning is particularly mischievous, for it stands to revitalize the applicability of breach of warranty claims arising from *known or knowable design defects* in the prescription drug industry in direct contravention of our unanimous holding in *Brown*.

For the same reasons applied to prescription drug *design-defect* actions in *Brown,* I do not believe a claim of breach of an implied warranty of fitness would survive adoption of *Brown*'s rationale to the *failure-to-warn* claims in this case. In any event, the parties are still at the pretrial pleading stage in this litigation. The complaint broadly alleges the defendants impliedly *and expressly* warranted that the drug Halcion was fit for its intended use and of merchantable quality notwithstanding their knowledge of its serious side effects, and there are few facts developed in the record to substantiate the pleaded claims one way or the other. As such, I would affirm the judgment of the

Court of Appeal to the extent it overturned the trial court's order sustaining the demurrer to the cause of action alleging breach of express warranty.

Accordingly, I would find that the trial court properly sustained Upjohn's demurrer to plaintiff's complaint for failure to state causes of action for strict liability or breach of implied warranty, and that the Court of Appeal erred in overturning that ruling.

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